HHS HEALTH RESEARCH PLANNING

HEALTH RESEARCH ACTIVITIES OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

Program Planning and Proposed Initiatives for Fiscal Year 1981

A Report of the HHS Steering Committee for the Development of a Health Research Strategy

December 1980

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service National Institutes of Health

Phase II Final Report

HHS HEALTH RESEARCH PLANNING

HEALTH RESEARCH ACTIVITIES OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

PROGRAM PLANNING AND PROPOSED INITIATIVES FOR FISCAL YEAR 1981

A Report of the HHS Steering Committee for the Development of a Health Research Strategy

December 1980

Including Minutes of the Steering Committee for June 1979 (Appendix I), Which Continue the Public Record of Documents Begun in Volumes 1 and 2 and in the December 1979 Report of the HEW Health Research Planning Series

---

NIH Pub. No. 81-2319

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
National Institutes of Health

August 1980

HHS STEERING COMMITTEE FOR DEVELOPMENT OF A HEALTH RESEARCH STRATEGY

Patricia Roberts Harris
Secretary of Health and Human Services

CHAIRMAN

Dr. Donald S. Fredrickson
Director
National Institutes of Health

EXECUTIVE SECRETARY

Dr. Joseph G. Perpich
Associate Director for Program Planning and Evaluation
National Institutes of Health

MEMBERS

STAFF

Office of the Secretary

Mr. John L. Palmer
Assistant Secretary for Planning and Evaluation
Designate

Mr. Christopher Bladen
Director of Health Evaluation
Office of Planning and Evaluation

Ms. Cheryl F. Austein
Office of the Assistant Secretary for Planning and Evaluation/ Health

Mr. Frederick Bohen
Assistant Secretary for Management and Budget

Ms. Ellen Wormser
Director, Division of Health Budget Analysis
Office of the Assistant Secretary for Management and Budget

Health Care Financing Administration

Mr. Howard N. Newman
Administrator

Dr. Judith R. Lave
Director, Office of Research

Office of the Assistant Secretary for Health

Dr. Julius B. Richmond
Assistant Secretary for Health and Surgeon General

Mr. Charles Miller
Deputy Assistant Secretary for Health Operations

MEMBERS	STAFF
Office of the Assistant Secretary for Health (Cont.)	
Ms. Susanne A. Stoiber Deputy Assistant Secretary for Health Planning and Evaluation	Ms. Georgi Jones Director, Division of Health Research and Prevention Office of Health Planning and Evaluation
Office of Health Research, Statistics, and Technology	
Mrs. Ruth S. Hanft Deputy Assistant Secretary for Health Research, Statistics, and Technology	Dr. Donald Goldstone Associate Deputy Director for Medical and Scientific Affairs National Center for Health Services Research Dr. Joel Kavet Associate Director for Program Development Dr. Samuel P. Korper Associate Director for Legislation, Epidemiology, and the Environment
Alcohol, Drug Abuse, and Mental Health Administration	
Dr. Gerald L. Klerman Administrator	Mr. David Kefauver Acting Director, Division of Science
Center for Disease Control	
Dr. William H. Foege Director	Dr. Walter R. Dowdle Assistant Director for Science Mr. Norman W. Axnick Director, Office of Program Planning and Evaluation Dr. Kenneth Bridbord Director, Office of Extramural Coordination and Special Projects National Institute for Occupa- tional Safety and Health

MEMBERS	STAFF
Food and Drug Administration	
Dr. Jere E. Goyan Commissioner	Dr. Michael Goldberg Special Assistant to the Director
	Dr. Constantine Zervos Director, Scientific Liaison and Intelligence Staff
Health Services Administration	
Dr. George Lythcott Administrator	Mr. Ronald H. Carlson Associate Administrator for Planning, Evaluation, and Legislation
Health Resources Administration	
Dr. Henry A. Foley Administrator	Mr. Lyman Van Nostrand Director, Division of Planning Office of Planning, Evaluation, and Legislation

EX OFFICIO MEMBER	STAFF
Mr. Randolph S. Kinder Executive Secretary Office of the Secretary	Ms. Laurie Feinberg Policy Coordinator Executive Secretariat Office of the Secretary

CONTENTS

APPENDICES

CHAIRMAN'S OVERVIEW

This document represents the conclusion of the second phase of a process for developing a health research strategy for the Department of Health and Human Services. The first phase resulted in the announcement by the Secretary in August 1979 of a set of principles to guide the Department in its conduct and support of health research programs. The second phase was one of interagency research planning. The results are described in two sequential reports.

The first report, HEW Health Research Planning: Current Efforts and Proposed Initiatives, dated December 1979, was released as a draft for public comment in February 1980 and, further, was the subject of a critique by the Institute of Medicine. The second report--closely related to the first, but intended to stand alone--is the present document. As now conceived, this could be the model for an annual report on HHS health research planning for release in January after the submission of the President's Budget.

The February report was in two parts. First, each of nine agencies within HHS provided an analysis of the organization, conduct, and support of its health research activities. The second part described special interagency research initiatives addressing some of the important problems in health science facing America and the world today. Secretary Harris directed the HHS Steering Committee to evaluate carefully all public comments received--including those from the IOM--and to revise the document as necessary. She also asked the Committee to investigate how its planning process might best be integrated into Departmental planning and budget activities. The present document attempts to address these concerns.

The IOM, in its critique of the Steering Committee's February document, raised fundamental issues of planning for Federal health research programs that can be treated here only partially. In the view of the IOM, the Steering Committee's planning document reflected substantially less than the global approach anticipated on the basis of the health research principles released in August 1979. The Secretary had urged the Government and the research community to embark on the preparation of a long-range health research plan. The IOM felt that the report, as an assumed response to this, failed to include research plans of sufficient breadth and specificity for the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration.

The IOM reviewers emphasized that a well-conceived plan would reflect consideration of scientific opportunities (i.e., the state of the art, the

potential for near-term breakthroughs, the interrelatedness with other research problems), the associated burden of illness, the public's perception of need, and the mission needs of regulatory as well as research agencies. The planners should consider the extent and distribution of research activities, which disciplines show special promise for advancing the public's health, what problems need more attention, and where duplication of activity was excessive and personnel or facilities were in need of further development or better utilization. The IOM concluded that a major effort is needed to synthesize answers to these questions from multiple sources, such as the report of the President's Biomedical Research Panel.

These are ideal goals, indisputably the horizons sought by the HHS agencies. However, the agencies can only move toward goals at the pace and degree of directness permitted by the realities of the annual appropriations cycle.

Many of the issues raised by the IOM are now being addressed very actively at the agency level, if not yet at the Departmental. The introduction to Part One of this document briefly describes the nature of each agency's research planning activities and how they relate to agency missions. The present HHS planning effort has increased the integration of some activities, and research coordination within the Department has never before been attempted on this scale. The Secretary is now being offered a context for her budget decisions on health research that is considerably broader than those made about each agency individually. The resulting convergence of planning and budget activities at many levels is one of the most promising aspects of the HHS research planning effort.

Also, for each of the agencies, the HHS planning process has resulted in a broadened concept of the health sciences which fuses the boundaries between traditional laboratory or clinic-oriented biomedical research and the fields of epidemiology, biostatistics, environmental science, health services research, and the behavioral and social sciences. These activities have also opened up the nature of budget planning within the Department to a much broader community with a major stake in the outcome. Revealed is a perspective on resource allocation other than that seen from the usual single focus on Congressional appropriations. Not only does one view the extensive planning and budgeting for health research that occurs throughout the year in the Department; also visible are the opportunities for nongovernmental participation in the planning process.

Beyond question, there are important issues in health research planning that require further attention. There is need to promote more productive interaction between public and private sectors; to strive continuously for increased effectiveness in the difficult area of coordination among related activities of different Federal departments and agencies; and--raising one's sights a bit higher--a need to explore additional opportunities for systematic sharing of ideas, information, and resources with other nations.

With respect to the future of health research planning in the Department, it is worth noting several other planning efforts that relate to or impact on HHS processes. For example, the National Science Foundation, in response to a Congressional mandate, is developing both an annual report on science and technology for the Federal Government and a five-year outlook. An important

functional area in these reports is health research. The Committee on Health and Medicine of the Federal Coordinating Council on Science, Engineering, and Technology provides another mechanism for highlighting health research needs and issues and for surveying pertinent activities of Federal health agencies. The coordinating work of this Committee may be especially helpful in the preparation of the health research section of the NSF report. Also, several sizable and productive efforts of pan-governmental coordination in the health sciences are already under way. These include research on the health effects of ionizing radiation and on the testing of chemicals for toxicity.

Thus, frame by frame, but persistently, a broader tapestry for health research planning is being woven. As planning processes intersect and agencies gain experience, more useful planning in a longer-term and more comprehensive mode should become possible. But for agencies operating within the Federal context, planning will always have its intrinsic limits.

Special Interagency Health Research Initiatives

Fifteen initiatives are described in Part Two. Eleven of these were a part of the document that went out for public comment in February, and four new ones were added in the July 1980 redraft. In the revision and expansion of earlier initiatives material, the Committee has attempted to respond to the Secretary's mandates, to public commentators, and to the IOM critique.

The IOM indicated, for example, that the following considerations should guide the selection of health research initiatives:

- Among the main criteria for priority should be scientific opportunity and the burden of illness, along with the public's perception of need and the needs of regulatory agencies;
- The application of the health research principles and the details of the application of the criteria for priority should be presented explicitly in the planning document;
- The health research principles should be in evidence at the level of agency selection of priority as well as in the final selection of Departmental priorities;
- The health research community should participate in the process of determining scientific opportunity; and
- Scientific excellence must be a principal criterion for the support of research.

These criteria have shaped the presentation of the initiatives. Initiatives are not always new; many represent problems under attack for years. All those selected here represent research programs that derive special force from the participation of multiple agencies. Commitments must be long-range and participation continuous; yet, the dedication of resources requires annual adjustments based on the overall allotment of resources to each of the participating agencies. The budget displays reflect the amount that each agency

identified as pertinent to the initiative for FY 1980 and, for FY 1981, the amount it felt it could dedicate to the initiative in that year, given certain assumptions about funding levels. Such agency commitments are, in effect, an expression of priority.

Perhaps not surprisingly, most of the initiatives in this document are in biomedical research, reflecting the heavy research investments of NIH and ADAMHA. But the intent is to advance where possible in all areas of health research. Moreover, it should be noted that the Department already has other high-priority "initiatives" with significant components of health research which have been launched wholly apart from Steering Committee activities. One of several prominent examples that may be cited is the Secretary's initiative in long-term care, which involves major collaboration in health services research between the Health Care Financing Administration and the Office of Health Research, Statistics, and Technology. Clearly, though, if this new health research planning process for the Department works effectively, it should stimulate health research in HHS agencies generally. In that case, such fields as epidemiology, biostatistics, health services research, and the behavioral and social sciences will be reflected more prominently in future research efforts.

As a final point, it is felt that the reaffirmation of commitments to these initiatives, and the search for new arrangements for cooperation, have an importance of their own. Those of us who have participated in three rounds of preparation of these reports have derived not only a better understanding of all the elements in HHS health sciences, but also a growing sense of how these elements can work effectively together.

Donald S. Fredrickson, M.D.
Chairman
HHS Steering Committee

Part One

HEALTH RESEARCH PLANNING AT THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

INTRODUCTION

In April 1978 the former Secretary of Health, Education, and Welfare initiated a major review and reappraisal of the Department's health research activities. The first phase of the initiative resulted in the announcement in July 1979 of a set of health research principles that would constitute a common point of reference for this assessment. In December 1979 the HEW Steering Committee for the Development of a Health Research Strategy issued its draft report Health Research Activities of the Department of Health, Education, and Welfare: Current Efforts and Proposed Initiatives. This report presented within a single framework a description of all the health research activities of the Department and identified for the Secretary's consideration a number of long-term interagency research proposals. At the Secretary's request, the draft was widely distributed for comment to the scientific and academic communities, the Executive Branch, and the Congress. It was subsequently revised in the light of these public comments, and the present report is the result of this process.

The report is in two parts. The first summarizes the health research planning activities of each of the constituent agencies of the Department. Both the agencies' FY 1981 plans for health research and the processes through which these plans were formulated are briefly described. The second part updates the interagency research initiatives. All budget information used in this report is from the FY 1981 President's Budget. (The continuing resolution changes became available after the Report's completion.)

In considering the Department's health research planning activities, it is important to recognize that HHS agencies pursue differing missions and that the significance of research for those missions varies considerably. These differing orientations impact profoundly on the conduct of HHS-wide research planning. Thus:

- The National Institutes of Health (NIH) and the National Center for Health Services Research (NCHSR) devote their efforts entirely to research or research-related activities, although of different kinds.

- The Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) has major research responsibilities, but also supports a range of professional training and service programs.

- The Center for Disease Control (CDC) assists State and local health authorities in containing communicable disease, providing protection against some environmental hazards, and improving occupational health and safety. Its research needs are very closely tied to this mission.

- The Food and Drug Administration (FDA), a regulatory agency, is primarily concerned with the safety of food, drugs, biological

products, therapeutic devices, and diagnostic products. FDA's interest in research is as a data base for regulatory decisions.

- The Health Services Administration (HSA) is concerned with issues related to the delivery of health services in an organizational and socioeconomic sense.

- The Health Resources Administration (HRA) is concerned with the supply, utilization, quality, and cost-effectiveness of health care resources as they affect the system itself and the health status of individuals.

- The Health Care Financing Administration (HCFA) is responsible for programs providing health care to the Nation's aged, poor, and disabled. It has the additional responsibility of ensuring that its beneficiaries receive quality health care that meets professional standards.

Differences in mission produce different needs. Not only must the types of research differ, but the significance of research in the agencies' programs will vary. Within NIH and NCHSR almost 100 percent of the budgets are devoted to research or research-related activities. For FDA, CDC, and ADAMHA, the research commitment ranges from 20 to 30 percent. For HSA and HRA it is about one percent for each, and for HCFA research represents about 0.2 percent of its appropriation and about 0.08 percent of its total funds (including trust funds). In FDA, moreover, research is conducted in support of regulatory activities, and in CDC it underpins both regulation and service functions. Clearly the research commitment of the Department's health-related agencies varies widely.

Related to the above is the concentration of Departmental funds for research in the several health agencies. Over 90 percent of HHS health research funds appear in NIH and ADAMHA appropriations, and NIH receives over 90 percent of the total for the two agencies. (It is a common misconception that NIH accounts for all the health research in the Department.) While the major research role of NIH is recognized in this planning process, the intent is to highlight equally the Department's other research missions and related activities.

The significance of differing missions was also revealed in the December draft document through application of the so-called SATT model* as a way of describing all of the Department's health research programs. This model, admittedly derived from a particular view of biomedical research, was suggested because it is content-free and could therefore, it was thought, encompass any health-science endeavor. It was applied with some reservations by ADAMHA and FDA. While not necessarily convinced that this was the best way to represent their own research, these agencies accepted SATT for cross-agency description. CDC and NCHSR strongly objected to use of the model as inapplicable or misleading for their programs. The device is not applied in an overall

*The acronym stands for Science Base, Clinical Application, Technology Transfer, and Training. It is defined in Appendix B of the Phase II report.

way in the present report, but the SATT categories continue to serve in describing some activities.

The kinds of research undertaken by the individual health agencies result from the political decisions that established their missions. Research is the means through which different ends are served. Therefore, while the health research missions and programs of NIH and ADAMHA loom large in the sum of the Department's research activities, each agency within the Department must ultimately do its own research planning.

Just as there is no centralized R&D budget in the Federal Government, there is no centralized health research budget in HHS. This document does not attempt to call for the internal reallocation of an agency's funds to meet centrally defined goals without, at the same time, reassessing the agency's total program. Thus, part of the planning problem is the integration of the objectives derived from centralized plans with the budgets of individual agencies. Central planning objectives that go beyond coordination and call for the expansion of agency programs in particular areas should compete for funds in the regular planning and budgeting process.

Ideally, research planning should be based on assessments of scientific opportunity and long-range societal goals. Thus, the Institute of Medicine, in its critique of the original draft document, notes that a well-conceived research plan would reflect important strategic considerations--the state of the art, the burden of illness, and so on. Without disagreeing with these general principles, one is not always clear how to apply them to the diverse programs and missions of the Department. For the present planning effort, the Committee has determined upon a more modest approach: to provide a mechanism through which coordination and collaboration can be enhanced in selected problem areas of shared mission concern and clear scientific opportunity.

Chapter 1

NATIONAL INSTITUTES OF HEALTH

Agency head:

Dr. Donald S. Fredrickson
Director
National Institutes of Health
Building 1, Room 126
Bethesda, Maryland 20205
(301) 496-2433

Planning contact:

Dr. Joseph G. Perpich
Associate Director for Program
Planning and Evaluation
Office of the Director
Building 1, Room 137
Bethesda, Maryland 20205
(301) 496-3152

Budget contact:

Mr. Norman D. Mansfield
Director
Division of Financial Management
Office of the Director
Building 1, Room 32
Bethesda, Maryland 20205
(301) 496-2567

Chapter 1

NATIONAL INSTITUTES OF HEALTH

Planning at NIH is a structured and integral part of the formulation and conduct of health research programs. The planning function establishes the framework through which goals, objectives, and research strategies are assessed, research priorities set, resource allocations made, new programs developed and implemented, and existing programs modified.

Each Institute has established its own planning process--and each responds to a common NIH process. These processes are designed to increase the probability that significant knowledge will be produced under a wide range of circumstances and will lead to safe and effective interventions in man. Underlying the planning of research programs are a number of common points of reference--namely, assessment of the state-of-the-art, of the scientific opportunities, and of the national significance of the problem. However, planning at NIH takes many different forms, depending upon the problem and how much is known about it. This variety of planning approaches reflects the great diversity and complexity in the many fields of inquiry that NIH supports and the processes through which knowledge is advanced.

Over the past several years, NIH has strengthened and improved its planning and evaluation activities in order to ensure that the most promising scientific opportunities are identified and pursued, that limited resources are effectively used, and that NIH programs are responsive to legislative mandates and broad health objectives established by the Department. A recent focus of these efforts has been to devise appropriate ways of involving a broader segment of the research community in the NIH planning process--particularly important in a period when national resources are not sufficient to meet all competing concerns and when biomedical research is becoming increasingly engaged with new ethical, legal, and social imperatives under public scrutiny.

Highlights of some of the factors considered and processes followed in planning NIH research programs and establishing priorities are summarized below.

Priority-Setting

Given the nature of health research and the scope of the research enterprise, priority-setting at NIH is necessarily a complex activity. Its essential strength stems from the diversity of factors, influences, and participants involved in the decision-making process. This activity is subject to

the constraints and stimuli of three basic forces--political, technical, and the momentum of prior investment.

Certain major public priorities are implicit in the structure of NIH. This organization reflects not only the intrinsic significance of the health problem, but the political strength of the constituency interested in it. The Congressional authorization and allocation process is the primary mechanism through which political and constituency groups influence research priorities and constitutes a primary measure of perceived social significance of diseases.

Technical considerations are based on the support of excellence and on judgment as to where research opportunity lies. Precise identification of areas for research emphasis is a difficult undertaking, particularly for basic research on fundamental life processes that underlie most disease. At any given moment, however, it is possible to achieve a reasonable degree of expert consensus on broad areas of need and opportunity as well as to identify individual projects worthy of support. A further refinement of this process is the identification of areas and projects of especially high program relevance.

The momentum of prior investment is a strong force for continuation of certain priorities. In part, this is attributable to the long-term nature of the problems presented by chronic diseases and the fact that solutions come slowly. In part, it results from the need to capitalize on existing investment by identifying where further resources will yield the highest returns of increased knowledge. Within the context established by this set of forces, competition for scarce resources occurs at all programmatic and organizational levels throughout the NIH planning and budgeting cycle.

Institute Planning Processes

Each Institute conducts its own planning process through which future program directions are identified, research priorities established, and resource allocations considered. While there are differences, each Institute in planning its programs considers many similar factors. Differences in planning approaches can be attributed to the nature and scope of the research activity being planned, to the internal resources available, and to the individual planning requirements imposed by legislation. The Institute planning activities result in a diverse array of program documents that provide extensive information on program plans and research opportunities.

In general, each Institute annually--

- Assesses its goals, objectives, and the research strategies designed to meet those goals;
- Reviews program progress, the state-of-the-art, evaluation studies, and various reports addressing particular program areas;
- Assesses scientific opportunities;
- Attempts to determine the national significance of the health problems under consideration;

- Reviews program contributions to broader health objectives established by PHS and HHS;
- Reviews responsiveness of programs to Congressional mandates; and
- Discusses or reviews plans with the Institute's National Advisory Council.

All of the above factors influence the setting of priorities at the Institute level. None are mutually exclusive, nor are they necessarily weighted equally. Consideration of these factors does provide a reasonable basis for recommending program emphasis and direction to the NIH Director as part of the central NIH planning process.

Central NIH Planning Process

This process begins in September of each year and is essentially completed with the publication of the NIH Research Plan in the spring. The major elements in the planning process are as follows:

- The core of the process consists of a systematic set of meetings that provide a forum for interaction and decision-making between the NIH Director and the NIH Institute Directors, each with his or her respective senior staffs. This interaction focuses on each Institute's program plans, opportunities for research progress, proposed allocation of resources, legislative proposals, and major program issues. Inevitably, the meetings also enhance the integration of the planning, evaluation, financial, and legislative functions. For each Institute the outcomes of this process are a refined program plan and a planning budget level. The planning meetings initiate action leading to the resolution of program issues, or to further work on them, and they represent a mutually useful briefing in preparation for Congressional hearings.
- A number of health problems cut across the categorical lines of the Institutes and require a somewhat different planning effort. These problems are reviewed within the same structure as that provided for the individual Institutes, and each Institute with an interest in the particular health problem participates. The review centers on the current status of planning in these areas, including assessment of coordinating mechanisms in place, and on discussion of future activities.
- The budget and research planning processes are integrated at all points throughout the eight-month planning period. This integration provides NIH with a firmer planning base, a more realistic context in which to consider future program directions, and a more relevant structure around which decisions concerning research opportunities can be made. It also advances the NIH capability to develop the agency preliminary budget submission as a logical followthrough of the planning process.

This process was broadened for the first time this year to include in the Director's review sessions the members of the Institutes' Advisory Councils and the Director's Advisory Committee. The contributions of these individuals added substantially to NIH consideration of a number of issues. Their participation provided an opportunity to hear firsthand about many of the stresses under which research institutions and universities are now operating and the possible impact on the community of any changes that NIH may plan as resources dictate.

The central NIH planning process was recently evaluated by the Office of the Director in concert with the Institutes to determine how it could be further improved. The changes proposed as a result of this review are now being implemented for the FY 1983-85 planning cycle.

FY 1981 Budget--Summary
(In Thousands)

Extramural:	
Research grants	$1,714,443
Research training	159,484
Contracts	374,881
Other	524,351
Subtotal	$2,773,149
Intramural	394,147
HHS Health Research Initiatives:	
Stabilizing the Science Base	(1,713,800)
National Toxicology Program	(58,040)
Effects of Radiation	(15,020)
Population	(102,371)
Smoking and Health	(16,900)
Alzheimer's Disease	(13,933)
Nutrition	(153,683)
Prevention of Occupational Disease	(19,099)
Prevention of Reproductive Effects	(5,000)
The Individual Consumer in Health	(16,328)
Accelerated Development of New Vaccines	(10,619)
Other	323,151
Total	$3,490,447

National Institutes of Health

FY 1981 Plan for Health Research

Introduction

The National Institutes of Health--the principal medical research arm of the Federal Government--provides almost 88 percent of the total investment of the Public Health Service in health research activities. About 85 percent of the annual NIH budget goes to support research and research training at universities, medical centers, hospitals, and other research institutions. About 1,200 institutions in every State and in several foreign countries receive NIH funds. About 10 percent of the NIH budget is devoted to the laboratory and clinical investigations of the intramural program--one of the largest and most distinguished in the world. Altogether NIH conducts or supports an estimated 42 percent of the Nation's health research and development.

Budget

The 1981 budget for NIH is approximately $3.5 billion and would provide 11,859 positions. This budget represents an increase of $91 million and 62 positions over the 1980 revised request.

FY 1981 Budget--by Mechanism
(In Thousands)

Mechanism	Amount
Research project grants	$1,714,433
Research center grants	388,212
Other research grants	186,139
Training grants	159,484
Research and development contracts	374,881
Intramural research	394,147
National Library of Medicine	44,389
Direct operations	144,257
Other	134,505
Total NIH	$3,490,447

National Institutes of Health

FY 1981 Budget--by Institute
(In Thousands)

Institute	Amount
Aging	$ 74,317
Allergy and Infectious Diseases	226,412
Arthritis, Metabolism and Digestive Diseases	361,211
Cancer	965,105
Child Health and Human Development	215,031
Dental Research	69,951
Environmental Health Sciences	93,769
Eye	115,562
General Medical Sciences	328,139
Heart, Lung, and Blood	532,799
Neurological and Communicative Disorders and Stroke	246,807
National Library of Medicine	44,389
Research Resources	173,878
Fogarty International Center	9,138
Office of the Director	22,189
Buildings and Facilities	11,750
Total NIH	$3,490,447

Program Strategy

The budget for FY 1981 reflects the intent of NIH to implement the Administration's commitment to sustain activities designed to stabilize the science base. A major part of the NIH science base consists of research supported through investigator-initiated research project grants. These have been selected for special emphasis to underscore the Nation's determination to maintain fundamental research as an indispensable long-term societal investment. The ability of NIH to fund annually about 5,000 competitive research project grants will contribute substantially to the assurance that the Nation's science base will not be eroded.

NIH recognizes, however, that research project grants represent only one element--albeit a crucial one--in the multifaceted approach required to provide balanced support for biomedical research. Although the science base forms the foundation from which new knowledge is generated, that knowledge must be translated into practical applications. Clinical trials must be conducted, technology must be moved into community settings and evaluated, new scientists must be trained, research resources must be maintained, centers of excellence must be preserved, and research information must be disseminated. All of these imperatives have been considered in the resource allocations for FY 1981, although the level of effort for each activity must be maintained at, or slightly below, the FY 1980 level in order to sustain the stabilization of the science base. The FY 1981 budget does, however, provide a modest level of funds for maintaining clinical research units and regional large-scale instrumentation facilities, for breeding nonhuman primates (now almost unobtainable from the customary foreign sources), for modernizing obsolescent laboratories, for pilot studies and short-term funding of young investigators, and for programs for minority scientists.

The intramural program is a valuable instrument in accomplishing the NIH mission and serves as a benchmark of excellence for our Nation's biomedical research community. The scientists, their supporting staffs, and the laboratory and clinical facilities together form an irreplaceable national resource. This plan reflects the need to maintain the intramural program at its current level of effort; to complete the Ambulatory Care Research Facility and continue the modernization of the NIH Clinical center; and to initiate a program to modernize the NIH laboratory buildings, many of which have been in use since 1940.

NIH provides for the training of approximately one-fourth of the scientists needed to replenish the pool of biomedical investigators. This includes the clinical scientists, always in short supply, who are essential for research involving patients. Last year, for the first time in six years, stipend levels were increased for training under the National Research Service Award program. Additional increases in stipend levels should be considered in the future to offset partially the effects of inflation.

Programs

Below are highly abbreviated descriptions of the Institute's plans for 1981. These descriptions are not intended to be comprehensive, nor do they necessarily touch upon all anticipated areas of emphasis.

National Institute on Aging

FY 1981 Budget
(In Thousands)

Activity	Amount
Aging	$55,622
Intramural research	13,359
Direct operations	3,514
Program management	1,822
Total	$74,317

The mission of the National Institute on Aging is to foster biomedical, social and behavioral research designed to increase our knowledge about the aging process and to reduce dependency and improve life for older people.

During FY 1981 the Biomedical and Clinical Research Program will expand its support of research in such areas as the neuroscience of aging, hearing and sleep disorders associated with aging. Priority will be given to maintaining the availability of crucial research resources such as colonies of old animals, cell banks and other biological materials.

The Social and Behavioral Research Program will stress research which focuses on the dynamic nature of aging, such as the inter-relatedness of old age with earlier ages, the variability of aging within and across societies, and the multiple facets of aging.

The Epidemiology and Biometry Program is planning studies of senile dementia, the last days of life, financial distress and health problems of the rural aged. The Intramural Research Program will continue studying metabolic changes associated with age, nutrient utilization, brain metabolism of drugs, and cerebral function in relation to aging, cerebrovascular disease, and dementia.

National Institutes of Health

National Institute of Allergy and Infectious Diseases

FY 1981 Budget
(In Thousands)

Activity	Amount
Immunology; allergic and immunologic diseases	$ 68,578
Microbiology and infectious diseases	108,439
Intramural research	37,664
Direct operations	9,395
Program management	2,336
Total	$226,412

The mission of the National Institute of Allergy and Infectious Diseases is to conduct and support research on all infectious diseases of man, including those of international health importance. The Institute is also the major source of support for research on allergic diseases and a primary supporter of research on the immune system and diseases caused by its disorders. Transplantation biology is an important area, and the Institute operates a serum bank to supply HLA typing sera to researchers who are pursuing improved methods for transplanting organs.

In carrying out its mission, the Institute supports basic research in virology, immunology, bacteriology, mycology, and parasitology, as well as clinical epidemiologic studies on infections, asthma, and allergic diseases. Its clinical research programs are oriented to improving methods for prevention, diagnosis, and treatment. These include antiviral drug therapy, vaccine development, and immune regulation. It also supports research manpower development in these fields.

The Institute has the responsibility for implementation of the Guidelines for Recombinant DNA research and for risk assessment of that research.

The budget request for 1981 will support ongoing commitments for basic research and provide for stabilizing the number of awards for regular research projects at about the level of previous years. Commitments to research targeted at such major health objectives as vaccine and antiviral drug development, other clinical trials, and epidemiologic studies will be maintained. Research training, to ensure a continuing supply of newly trained scientists and physicians, will be supported at the commitment level.

National Institute of Arthritis, Metabolism and Digestive Diseases

FY 1981 Budget
(In Thousands)

Activity	Amount
Arthritis; bone and skin diseases	$ 60,266
Diabetes, endocrinology, and metabolism	130,976
Digestive diseases and nutrition	56,666
Kidney diseases, urology, and hematology	57,993
Intramural research	41,727
Direct operations	12,159
Program management	1,424
Total	$361,211

NIAMDD is responsible for research in 10 major program areas, and this research encompasses most of the serious chronic diseases besetting Americans. The arthritis research program will continue to expand knowledge of how rheumatic diseases, connective tissue diseases, and associated musculoskeletal disorders develop. The Institute will pursue one of the major advances of the decade--the discovery of a genetic marker for ankylosing spondylitis, a form of spinal arthritis that primarily affects young men--and will support new and continuing studies on the design and fabrication of joint prostheses and the improvement of biomaterial components.

In the diabetes program, the Institute plans to continue to support studies that have identified genetic factors apparently associated with both the insulin-dependent and non-insulin-dependent forms of diabetes. There will be continued support of three Diabetes-Endocrinology Research Centers and of eight Diabetes Research and Training Centers. The endocrinology program supports basic and clinical research on the endocrine glands and their hormonal secretions.

The Institute will continue to support research into the causes, treatment, diagnosis, and prevention of disorders of organ systems associated with the gastrointestinal tract, including the salivary glands, esophagus, stomach, pancreas, liver, gallbladder, and small and large intestines. Specifically, research to determine the causes and treatment of certain diseases such as esophagitis, peptic ulcer, pancreatitis, ulcerative colitis and regional ileitis (Crohn's disease), malabsorption syndrome, gallstones, and cirrhosis will

be supported. Research support will continue in hematology and into diseases and disorders such as urolithiasis (kidney stones), nephrosis, benign prostatic hyperplasia, polycystic kidney disease, diabetic nephropathy, kidney damage induced by drugs and/or environmental toxins, and congenital malformations.

National Cancer Institute

FY 1981 Budget
(In Thousands)

Activity	Amount
Cause and prevention research	$285,317
Detection and diagnosis research	56,146
Treatment research	312,618
Cancer biology	141,432
Cancer centers	68,371
Research manpower development	35,490
Construction	3,941
Cancer Control	61,790
Total	$965,105

The National Cancer Institute is the Federal agency responsible for administering and coordinating the National Cancer Program (NCP) established by the Congress in 1971. The goal of the NCP is to develop means to reduce the incidence, morbidity, and mortality of cancer.

The budget request for 1981 provides support for a continued and balanced program in cancer prevention, detection, treatment, and basic research, in addition to fostering the development of a network of community and national resources for cancer research and the care and support of cancer patients.

Research into cause and prevention involves laboratory, field, and demographic studies on the causes and pathogenesis of cancers and the development of means for their prevention. Detection research includes the development of procedures for screening apparently normal population groups considered to be at high risk for cancer. Diagnostic research is directed toward development and improvement of methods to determine, in individual patients, the presence, exact location, extent, and specific type of cancer. Related research in prognosis seeks to improve the ability to predict, in an individual patient, the probable growth, future spread, and response to treatment of cancer. Treatment research, directed toward the development of the means to cure can-

cer or to maintain control of cancer in patients who are not cured, centers on the search for antitumor agents and on combined modalities utilizing drugs singly or in combination with surgery, radiotherapy, or immunotherapy. Research in cancer biology is devoted to the accumulation of knowledge of the fundamental and cellular changes accompanying the initiation of division, growth, and regulation of normal cells and the abnormal growth of malignant cells.

The cancer control program supports projects designed to reduce the incidence, morbidity, and mortality from cancer by identifying potentially applicable technologies, testing and evaluating them, and then demonstrating and promoting their use. The resource development program provides grant and contract support for the NCP to assure the continued availability of facilities and manpower to support cancer research and control programs in an efficient and effective manner.

National Institute of Child Health and Human Development

FY 1981 Budget
(In Thousands)

Activity	Amount
Research for mothers and children	$105,596
Population research	75,996
Intramural research	22,271
Direct operations	9,108
Program management	2,060
Total	$215,031

The National Institute of Child Health and Human Development is the only institution that combines research on maternal and child health with studies in the population sciences to address health and behavioral problems of women, children, and families. A major objective of research programs is to provide all couples safe, effective, and inexpensive means to regulate fertility and to ensure that all infants are provided from conception and birth an opportunity for healthful and productive adulthood.

The budget request for FY 1981 looks toward Institute programs that will contribute to the health of mothers and children and to the quality of family life. Research for mothers and children, and population research, the two major programs of the Institute, will both be increased for support of competing research projects in FY 1981. This will allow continuation of critical research efforts in clinical nutrition and early development, human learning and behavior, mental retardation, and developmental disabilities. In

the population area, reproductive, social, and behavioral sciences will receive support.

Training programs and research and development contracts will be supported in FY 1981 at the commitment base level. Projects that will be supported in contraceptive development include clinical trials to test the utility of synthetic hormones of the brain as ovulation inhibitors. Contraceptive evaluation includes studies on the relationship between oral contraceptive use and the occurrence of various cancers.

National Institute of Dental Research

FY 1981 Budget
(In Thousands)

Activity	Amount
Caries	$11,378
Periodontal diseases	8,948
Restorative materials	4,170
Craniofacial anomalies	8,501
Pain control and behavioral studies	3,798
Soft tissue stomatology and nutrition	6,859
Dental research institutes	7,476
Intramural research	13,720
Direct operations	3,836
Program management	1,265
Total	$69,951

In its overall program, the National Institute of Dental Research currently gives priority to basic and applied research in six categorical areas: dental caries, periodontal diseases, soft tissue stomatology and nutrition, craniofacial anomalies, restorative materials, and pain control and behavioral studies.

The National Caries Program conducts research directly and supports extramurally research in four strategy areas: combating the microbial agent; enhancing tooth resistance; improving diet and nutrition; and mechanisms for improving delivery of preventive methods. With respect to periodontal diseases,

their etiology is less understood than that of dental caries. For this reason, research has focused on the role of infectious and immune processes. Emphasis in the area of craniofacial anomalies is on the expansion of knowledge related to early embryonic craniofacial development, biochemical and molecular alterations leading to oral-facial clefts, and treatment modalities.

Continued support will be given to research on etiology and epidemiologic factors associated with oral ulcerative disease, oral cancer, disturbances of mineral metabolism, and nutritional factors in oral health. The development of improved dental materials and restorative procedures will continue. Because pain is symptomatic of many oral-facial conditions and can be associated, together with fear anxiety, with dental treatment, the Institute plans to continue its support of studies examining the cause and mechanisms of oral pain, as well as its prevention and therapy.

Associated with the above strategies is a need for behavioral and social research that focuses on aspects of epidemiology, prevention, diagnosis, and treatment for each of the oral diseases and conditions. This latter area constitutes an increasingly important new activity for NIDR.

National Institute of Environmental Health Sciences

FY 1981 Budget
(In Thousands)

Activity	Amount
Prediction, detection, and assessment of environmentally induced diseases	$24,416
Mechanisms of environmental diseases and disorders	17,491
Research and manpower development resources	16,597
Intramural research	30,292
Direct operations	2,615
Program management	2,358
Total	$93,769

The National Institute of Environmental Health Sciences is the principal Federal agency supporting research, and the training of research manpower, in the area of effects of chemical, physical, and biological environmental agents on human health.

The budget for FY 1981 will continue grant-supported research and manpower programs concerned with the nature, location, and extent of environmental pollutants; the nature and extent of the exposed populations; the interactions of the various pollutants; and how and why disease and disorder produced by the various chemical, biological, and physical environmental agents occur. During FY 1981 NIEHS will attempt to encourage the submission of grant applications in research areas that include determining the incidence and prevalence of environmentally induced disease, improving chemical toxicity test methodology, and developing new tests--both short-term animal tests and *in vitro* tests for toxic endpoints, such as behavioral deficits and genetic mutations.

Investigator-initiated research in epidemiology will also be emphasized. Three areas identified for increased emphasis are (1) nonionizing radiation; (2) immunotoxicity studies aimed at developing information on how and why toxic chemicals, natural or manmade, attack an organism's immune system and negatively affect the ability of this system to respond to biological and biochemical insults; and (3) studies to develop better methods to extrapolate animal test data to exposure of man.

The 1981 budget request includes additional positions and increased funds to support the occupancy and operation of the new NIEHS facility in Research Triangle Park, N. C. It also provides funds for the continuation of ongoing National Toxicology Program research projects.

National Eye Institute

FY 1981 Budget
(In Thousands)

Activity	Amount
Retinal and choroidal diseases	$ 43,958
Corneal diseases	14,653
Cataract	10,187
Glaucoma	11,570
Sensory-motor disorders and rehabilitation	20,699
Intramural research	10,210
Direct operations	3,030
Program management	1,255
Total	$115,562

The goal of the National Eye Institute is to improve the prevention, diagnosis, and treatment of visual disorders, thereby alleviating suffering and reducing the expense of medical care and other social and economic costs. The retinal and choroidal diseases program will continue to support research to acquire knowledge of how the retina functions normally and how it is damaged by disease and to develop animal models of various retinal diseases. A major initiative in the corneal diseases program will be to stimulate more research on ocular immunology.

Research on cataract attempts to identify the causes of this disease and to develop methods for its prevention and improved treatment. Preliminary trials of aldose reductase inhibitors, which have been used successfully to slow or prevent cataract formation in diabetic laboratory animals, were begun in diabetic patients in FY 1980 and will continue into FY 1981. Support will continue for research on the biological processes that result in cataract formation and on the sequence of events that may be required for cataract delay or reversal.

The glaucoma program supports research to determine the causes of elevated intraocular pressure, to improve medical treatment to prevent or forestall loss of vision, and to develop alternative means of treating elevated eye pressure. Basic studies on aqueous hydrodynamics will shift increasingly from animal to human research. Tissue culture of trabecular meshwork will be pursued, and the search will continue for valid animal models, especially primate, of different kinds of glaucoma. The sensory-motor program supports laboratory and clinical studies on the development and function of those activities of the brain and the eye muscles that make vision possible. Research on applying psycho-physical testing to the diagnosis of retinal and neurophthalmic disorders will be emphasized.

National Institute of General Medical Sciences

FY 1981 Budget
(In Thousands)

Activity	Amount
Cellular and molecular basis of disease	$119,708
Genetics	111,080
Pharmacological sciences	40,572
Physiology and biomedical engineering	43,005
Minority access to research careers	3,621
Intramural research	579
Direct operations	7,937
Program management	1,637
Total	$328,139

The National Institute of General Medical Sciences has responsibility for focusing attention not on specific categorical diseases such as cancer or diabetes, but on basic underlying questions of cell biology, genetics, and pharmacology. The Institute also provides support for research in a few highly important problem areas, such as burn and trauma research and instrumentation development, but, even here, the objective is to gain new knowledge at the most basic levels--e.g., to search for the molecular and biochemical impact of severe burns.

The budget request for FY 1981 will provide for the continuation and expansion of basic research studies aimed at gaining fundamental knowledge in the areas of cell biology, genetics, and pharmacology. Investigator-initiated research grants will be awarded to support studies in such areas as cell regulation, cell differentiation and growth, recombinant DNA technology, pharmacogenetics, and instrument and method development. Additional emphasis will be placed on research related to trauma and burns, including the total body response to trauma, mitigation of pain, and the fundamental aspects of wound healing and biological repair.

In order to assure an adequate future supply of high-quality basic biomedical scientists, NIGMS will continue to provide support for individual and institutional research fellowship awards under the National Research Service Act (NRSA). Two components of the NIGMS training activity are special points

of focus which will continue to receive support. These are the Medical Scientist (M.D.-Ph.D.) Training Program and the Minority Access to Research Careers (MARC) Program.

National Heart, Lung, and Blood Institute

FY 1981 Budget
(In Thousands)

Activity	Amount
Heart and vascular diseases	$308,012
Lung diseases	76,773
Blood diseases and resources	74,934
Intramural research	41,477
Direct operations	25,930
Program management	5,673
Total	$532,799

As mandated in the National Heart, Blood Vessel, Lung, and Blood Act of 1972, the Institute's mission is ". . . to advance the national attack against diseases of the heart and blood vessels, the lungs, and blood. . .." NHLBI is responsible for the major share of U.S. research in heart, blood vessel, lung, and blood diseases, as well as for the management of the Nation's blood resources. The research efforts of the NHLBI are organized into three major categories: heart and vascular diseases, lung diseases, and blood diseases and resources. Some selected planned activities in these areas for 1981 follow:

Heart and vascular diseases continue to be the leading cause of death in this country. The Institute's research activities are directed toward a better understanding of the etiology of heart disease and the application of this information to more effective means of diagnosis, treatment, and prevention. Increased understanding of the basic mechanisms and physiological systems that control the atherosclerotic process and blood pressure, and the means by which they can affect the development of coronary heart disease, are of great priority. Among the planned activities are improving techniques for the diagnosis and treatment of peripheral vascular diseases, increasing knowledge of the pathogenesis of cerebrovascular disease, and developing noninvasive instrumentation to facilitate the diagnosis and observation of disorders of the large and small vessels.

Research specifically addressed to heart disease is concerned with improving the recognition and assessment of latent and overt coronary disease, developing techniques for reducing heart muscle damage due to myocardial infarction, and assessing methods to prevent sudden cardiac death; understanding the

mechanisms involved in arrhythmias, with particular attention to methods of identifying persons at heightened risk and characterizing the process by which chronic coronary artery disease is converted into acute forms; developing improved techniques for the recognition of congenital and rheumatic heart disease; elucidating the causative factors and mechanism in cardiomyopathies; and research, development, and evaluation of short- and extended-term implantable circulatory-assist devices for clinical use.

Lung diseases affect both the young and the old. Research efforts in lung diseases are designed to increase understanding of the normal structure, biochemistry, immunology, cell biology, and physiology of the developing and adult respiratory system, and to determine how these are altered prior to clinical onset and during the course of pulmonary disease; to seek ways to prevent and control chronic obstructive lung diseases (e.g., emphysema and chronic bronchitis) by delaying or reversing disease progression through greater knowledge of pathogenesis, and through improved techniques for early diagnosis and more effective management; to prevent pediatric pulmonary diseases (e.g., respiratory distress syndrome, cystic fibrosis, and bronchiolitis) through increased knowledge of the underlying disease process; to prevent fibrotic and immunologic lung diseases through better understanding of specific airborne hazards and of the mechanisms by which they induce lung injury; to improve the diagnosis and management of acute respiratory failure in the adult through better understanding of the structural, biochemical, and physiological mechanisms of acute lung injury; and to elucidate mechanisms underlying the development of pulmonary edema, pulmonary hypertension, and corpulmonale, and bring this knowledge to bear in diagnosis and treatment.

Blood diseases and other problems of blood are intimately related to cardiovascular and pulmonary diseases. Research is being conducted to increase knowledge of the coagulation system, with the aim of reducing disability and death from occlusive arterial and venous thrombosis, alleviating the symptoms of hemophilia, and developing therapy for congenital and acquired platelet disorders; to improve the treatment of thalassemia and aplastic anemia; to investigate the pathophysiology of sickle cell disease and improve methods of clinical care; to develop an adequate supply of high-quality blood; and to advance basic understanding of the immunology and genetics of transplantation biology to improve clinical application.

Research training is crucial to the accomplishment of NHLBI goals. The Institute will continue to support NRSA individual and institutional research fellowship awards and the special manpower development programs--e.g., Clinical Investigator Award, Preventive Cardiology Academic Award, Pulmonary Academic Award, and Minority Hypertension Research Development Summer Program--to help assure an adequate supply of physicians and academic investigators.

National Institute of Neurological and Communicative Disorders and Stroke

FY 1981 Budget
(In Thousands)

Activity	Amount
Communicative disorders	$ 34,940
Neurological disorders	79,485
Stroke and nervous system trauma	42,056
Fundamental neurosciences	37,100
Intramural research	39,144
Direct operations	12,184
Program management	1,898
Total	$246,807

The mission of the National Institute of Neurological and Communicative Disorders and Stroke is the support and conduct of research and research training to further understanding of the functioning and disorders of the nervous system, including the brain, spinal cord, nerves and muscles, hearing, and human communication.

Communicative Disorders. Fundamental brain and peripheral organ (ear) processes will be explored to develop new knowledge on language development and sensory disorders, with the ultimate objective of identifying means to improve or restore communicative abilities in hearing--impaired and language-impaired children and adults.

Neurological Disorders. Efforts will continue on the identification of currently unknown causes of many neurological disorders, such as possible viral agents or genetic defects. Research will be expanded on the degenerative diseases of middle and later life such as Huntington's disease, on demyelinating diseases, such as multiple sclerosis, and on the development of new antiepileptic drugs.

Stroke, Nervous System Trauma. Emphasis will be on the advancement of knowledge of the processes involved in nerve growth and central nervous system regeneration as a possible means for restoring function after injury.

Fundamental Neurosciences. Research in the fundamental neurosciences explores the mechanisms responsible for normal functioning of the human nervous system and the basic pathophysiology of its diseases and disorders.

Intramural Research. The scientific staff will pursue the most promising lines of research in neurochemistry, neuropharmacology, immunology, and virology.

National Library of Medicine

FY 1981 Budget
(In Thousands)

Activity	Amount
Medical library assistance	$ 9,831
Intramural	29,967
Lister Hill National Center for Biomedical Communications	(4,805)
National Medical Audiovisual Center	(4,518)
Library operations	(17,599)
Toxicology information	(3,045)
Direct operations	1,827
Program management	2,764
Total	$44,389

The budget request for FY 1981 will provide support for programs to assist the advancement of medical and related sciences through the collection, dissemination, and exchange of information important to the progress of medicine and health. The mission of NLM is carried out through several programs:

- The Medical Library Assistance Program supports the development of medical library resources, research and training in biomedical communications and biomedical librarianship, and the publication of medical/-scientific works;
- The Lister Hill National Center for Biomedical Communications conducts research and development in the application of computer and communications technologies for improved health care delivery and to aid health professional education;
- The National Medical Audiovisual Center improves the quality and promotes the use of biomedical audiovisuals for primary and continuing health professional education;

- Library Operations acquires, preserves, organizes, and disseminates biomedical literature; and
- The Toxicology Information Program improves information transfer for the protection of health by developing communications systems for toxicologic and pharmacologic information.

Division of Research Resources

FY 1981 Budget
(In Thousands)

Activity	Amount
Clinical research	$ 59,636
Biotechnology research	18,908
Laboratory animal sciences and primate research	25,802
Biomedical research support	47,146
Minority biomedical support	16,817
Direct operations	4,367
Program management	1,202
Total	$173,878

The Division of Research Resources administers multicategorical programs to provide many different kinds of research resources to serve the diverse populations of biomedical scientists. These resources, which are not generally available through other NIH mechanisms, reduce the national costs of research and improve both the quality and quantity of new biomedical knowledge.

The budget request for FY 1981 will provide for the continuation of research resources and centers to support the nationwide biomedical research effort. The networks of Clinical, Biotechnology, and Primate Research Centers will continue their multicategorical operations, providing unique research environments, instrumentation, and opportunities to investigators at the cutting edge of biomedical research. Emphasis on Biotechnology Research Centers will increase, to provide additional shared research instrumentation facilities for researchers. Outdated and obsolete equipment at some resources will be replaced with state-of-the-art equipment, thus assuring the latest available technology. Research efforts needed to assure that research primate breeding goals are met will continue.

Commitments that result from modest expansion of the Minority Biomedical Support Program in 1980 will be met, and the funds available for Biomedical Research Support Grants (BRSG) will be increased in FY 1981. These BRSG funds will continue to support high priority areas such as pilot research projects, young investigators, and shared central resources that help to sustain research capacity.

Fogarty International Center

FY 1981 Budget
(In Thousands)

Activity	Amount
Gorgas Memorial Institute	$1,700
Direct operations	7,089
Program management	349
Total	$9,138

The Fogarty Center continues to serve as the integrating focus within the NIH for international activities.

In FY 1981 the Center will proceed with plans to establish an International Issues Study Program, to address issues and topics concerning the international aspects of biomedical and behavioral research, research manpower training, and the transfer of research results to health care systems.

The Fogarty Scholars-in-Residence Program will continue to provide outstanding scientists and other scholars the opportunity to focus their attention on broad aspects of important issues in biomedical research. While in residence at the Center, the scholars individually and collectively engage in collaborative research with NIH and university scientists.

The International Research Fellowship Program provides financial awards to foreign scientists at the postdoctoral level to enable them to pursue research studies in laboratories in the United States. The Senior International Fellowship Program provides awards to mid-career faculty members of U.S. universities to study abroad. In FY 1981 the number of fellowships available through both programs will decline somewhat from FY 1980 because of a shift of program emphasis toward the development of the Advanced Studies Program.

The Center will also continue to provide for operation of the Visiting Program and Guest Workers Program, whereby over 900 scientists from other countries come to work at NIH and share their ideas.

National Institutes of Health

A Selection of Recent Major Planning Reports of the National Institutes of Health

The following represents selected exemplary documents and should not be interpreted as a complete listing.

Office of the Director

National Institutes of Health Forward Plan, FY 1979-1983
National Institutes of Health Forward Plan, FY 1980-1982
National Institutes of Health Research Plan, FY 1981-1983, April 1979
National Primate Plan, by the Interagency Steering Committee, October 1978
NIH Consensus Development Conference Summaries, Volume I, 1977-1978
NIH Consensus Development Conference Summaries, Volume II, 1979
NAS Continuing Study of National Needs for Biomedical and Behavioral Research Personnel

National Cancer Institute

1977 Annual Plan of the National Cancer Institute for FY 1978-1983, November 1977
1978 Annual Plan of the National Cancer Institute for FY 1980-1984, December 1978
1979 Director's Report and Annual Plan for FY 1981-1985, March 1980
Subcommittee on Biological Response Modifiers of the Division of Cancer Treatment, Board of Scientific Counselors: Interim Report, September 1979

National Heart, Lung, and Blood Institute

Progress Report of the Cooley's Anemia Study, December 1977
Task Force Report: Prevention, Control and Education in Respiratory Diseases, November 1977
Heart, Lung, and Blood Research, Five Years of Progress: The Challenge Ahead
The Fifth Report of the Director of the National Heart, Lung, and Blood Institute, December 1977
Sixth Report of the Director of the National Heart, Lung, and Blood Institute, July 1978
Fifth Report of the National Heart, Lung, and Blood Advisory Council, August 1977
Sixth Report of the National Heart, Lung, and Blood Advisory Council, July 1978
National Program on Heart, Lung, and Blood Diseases--Progress Through Coordination, 2 volumes, November 1977
Report of the Work Group to Update the Report of the Task Force on Arteriosclerosis, January 1978
Report of the Task Force on Hypertension, 3 volumes, January 1978
Report of the Task Force on Heart Disease Epidemiology, June 1979

National Library of Medicine

Report to the National Library of Medicine from the Task Force on Review of the Extramural Research Grant Program, January 1978
Report to the Congress, Lister Hill National Center for Biomedical Communications, October 1979
Lister Hill Center Research Plan, March 1980

National Institute on Aging

Our Future Selves: A Research Plan Toward Understanding Aging, May 1977
Our Future Selves: Report of the Panel on Biomedical Research, May 1978
Our Future Selves: Report of the Panel on Behavioral and Social Sciences Research, May 1978
Our Future Selves: Report of the Panel on Research on Human Services and Delivery Systems, May 1978
Our Future Selves: Summary Reports, May 1978
Report of the Workshop on Pharmacology and Aging--Cosponsored by NIGMS and NIA, March 1978
The Older Woman: Continuities and Discontinuities--Report of the NIA and NIMH Workshop, October 1979
Aging and Medical Education, September 1978
Mammalian Models for Research on Aging--Report of the National Academy of Sciences Institute of Laboratory Animal Resources (in press)
Research Planning Workshop on Sleep and Aging, Sleep, Volume 1, 1979

National Institute of Allergy and Infectious Diseases

Virology Task Force Report, 6 volumes, 1978-1979
Asthma and Other Allergic Diseases Task Force Report, 2 volumes, 1979
Sexually Transmitted Diseases Study Group Report: Summary and Recommendations, May 1980
National Advisory Allergy and Infectious Diseases Council: Recommendations from the Sexually Transmitted Diseases Study Group Report, June 1980
Immunology Study Group Report, 1980

National Institute of Arthritis, Metabolism and Digestive Diseases

Annual Report of the NIAMDD Director on the Arthritis Program
Annual Report of the National Diabetes Advisory Board
Annual Report of the National Arthritis Advisory Board
Report of the National Commission on Digestive Diseases, January 1979
An Evaluation of Research Needs in Endocrinology and Metabolic Diseases, December 1979
Analysis of Priorities and Needs for Research in Dermatology, July 1979
Cystic Fibrosis: State of the Art and Directions for Future Research Efforts, 1978
Research Needs in Nephrology and Urology, 5 volumes, 1978

National Institute of Child Health and Human Development

A Pregnancy and Infancy Study Center, January 1979
Federal Research Activity in Mental Retardation: A Review with Recommendations for the Future, February 1977

Progress Report on the Five-Year Plan for Family Planning Services and Population Research Programs, September 1979
Annual Progress Report of the Center for Population Research
Ten Year Progress Report of the Center for Population Research, November 1978

National Institute of Dental Research

Evaluation of the NIDR Periodontal Disease Research Activity, April 1976
Evaluation of the NIDR National Caries Program, November 1979

National Institute of Environmental Health Sciences

Human Health and the Environment--Some Research Needs, 1977
NIEHS Facilities and Program Plans, June 1979
National Toxicology Program Annual Plan, FY 1979
National Toxicology Program Annual Plan, FY 1980

National Eye Institute

Vision Research - A National Plan: 1978-1982, The 1977 Report of the National Advisory Eye Council, May 1978

The following workshops to address scientific opportunities for the future were initiated as part of the implementation of the National Plan:

Workshop on Autoimmune Phenomena and Ocular Disorders, March 1980
Ocular Tissue Culture Symposium, October 1979
Workshop on Immunogenetics and Transplantation Immunity, December 1979
Workshop on the Role of Psychophysics and Physiological Optics in Ophthalmic Diagnosis and Patient Evaluation, September 1976

National Institute of General Medical Sciences

Biomedical Instrumentation Development: Recommendations of a Workshop on the Status and Future of Biophysical and Biochemical Instrumentation, September 1979
Future Directions for Biomedical Engineering Research: Recommendations of an Evaluation Workshop for the NIGMS Physiology and Biomedical Engineering Program, November 1978
Consultants Status Report: The Genetics of Common Diseases (Polygenic Diseases), December 1978

National Institute of Neurological and Communicative Disorders and Stroke

National Research Strategy for Neurological and Communicative Disorders, June 1979
Report of the Commission for the Control of Huntington's Disease and Its Consequences, October 1977
Plan for Nationwide Action on Epilepsy: Report of the Commission for the Control of Epilepsy and Its Consequences, June 1977
Central Nervous System Trauma Research Status Report, August 1979

Division of Research Resources

Assuring the Resources for Biomedical Research--An Evaluation of the Scientific Mission of the Division of Research Resources, October 1976
Primate Research Centers Evaluation Study, January 1979
National Survey of Laboratory Animal Facilities and Resources--Supporting Biomedical Research in the United States in Fiscal Year 1978, December 1979
Division of Research Resources Five Year Program Plan, 1982-1986, May 1980

Fogarty International Center

A Study of the Participation of Latin American Countries in the International Research Fellowship Program of the John E. Fogarty International Center for Advanced Study in the Health Sciences, December 1978
NIH International Research Fellowship Program, An Evaluation--1958-1977
Report of the Task Force to Assess the Mission and Functions of the Fogarty International Center, June 1979

Chapter 2

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

Agency head:

Dr. Gerald L. Klerman
Administrator
Alcohol, Drug Abuse, and
Mental Health Administration
Parklawn Building, Room 12-105
5600 Fishers Lane
Rockville, Maryland 20857
(301) 443-4797

Planning contacts:

Mr. Richard Millstein
Acting Director
Office of Program Planning
and Coordination
Parklawn Building, Room 13C-05
5600 Fishers Lane
Rockville, Maryland 20857
(301) 443-4564

Dr. Peter Kramer
Acting Director
Division of Science
Office of Program Planning
and Coordination
Parklawn Building, Room 12C-04
5600 Fishers Lane
Rockville, Maryland 20857
(301) 443-1680

Budget contact:

Mr. Kent Augustson
Director
Division of Financial Management
Parklawn Building, Room 12C-10
5600 Fishers Lane
Rockville, Maryland 20857
(301) 443-3846

Chapter 2

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

Health research and program planning within the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) results from a complex interaction between the Office of the Administrator (OA) and the three Institutes--the National Institute on Mental Health (NIMH), the National Institute on Drug Abuse (NIDA), and the National Institute on Alcohol Abuse and Alcoholism (NIAAA)--on the one hand, and between the Institutes and the scientific community and the public on the other.

The overall planning document for ADAMHA is the Five-Year Research Plan published December 1, 1979, after an 18-month series of consultations with experts within and outside the Government. In this document, ADAMHA uses as its rationale for differential resource allocation in research the HEW research planning principle of balancing need (burden of illness) and technical opportunity. The document cites the following as ADAMHA research priorities: training, neuroscience, behavioral science, treatment assessment, epidemiology and health services research, and prevention. In planning with the Institutes, OA has stressed a need for increased clinical research and for treatment assessment research in particular.

In addition, each of the Institutes interacts with the scientific community and the public in order to gauge emerging consensus in the scientific community regarding the most promising avenues of new research and to monitor the demands of program relevance and public responsiveness.

Within each Institute, evaluation of research proposed under the grant mechanism is subject to the peer review process, providing for consensual, evaluative judgment on the scientific merit of proposed research. Projects that are judged to be of the highest scientific merit are generally funded.

Within each Institute, planning is accomplished in stages beginning with the ADAMHA Five-Year Plan and advancing to more specific plans with the annual budget justification and plans required for submission to the Congress. Although this process is coordinated by OA, each Institute has developed its own internal mechanism for research planning.

National Institute of Mental Health

The Planning Process

NIMH procedures for mental health research planning and for the formulation of research priorities involve a variety of efforts. Institute research

programs and directions have been the subject of national-level reviews several times in the last eight years. Most recently the President's Commission on Mental Health's Research Task Panel conducted a detailed review of the mental health research effort. This included state-of-the-art assessments and recommendations for research emphasis in all the main elements of the research portfolio.

At the program level, NIMH staff are responsible for maintaining contact with researchers in the field, to be informed of the state of knowledge development in their program areas and to be cognizant of promising new directions. Program staff conduct workshops and contract for state-of-the-art papers and evaluations of specific research areas to guide program planning. Current efforts of this type include workshops and planning conferences on treatment of severe neurotic disorders, risk factors in schizophrenia and depression, economic analysis of the service delivery system, and unemployment, job stress, and related emotional problems.

At the Institute level, ongoing planning activities include regular meetings of the Research Advisory Group, a select group of NIMH research staff, to discuss program planning with the Director of NIMH. Task forces and work groups are convened for special research planning analyses.

In September 1979 the Director of NIMH appointed a Steering Committee on Research Organization and Management Issues, with representatives from the National Advisory Mental Health Council and the NIMH staff, to review the research in programs of the Institutes. The Final Report (January 1980) found that, in general, NIMH program staff had considerable interaction with the field, and reinforced this as a key planning ingredient. For special research program areas, the Committee recommended "cluster group planning," which would involve a joint staff-field scientist committee to review and evaluate the Institute's portfolio in designated research program areas and to assess future substantive directions and resource needs. In accord with this recommendation, a services research cluster planning group will be developed within the coming planning period. Additional cluster planning groups will be organized as the need arises for special research program analysis.

Mission and Programs

The purpose of the NIMH program is to develop new knowledge about mental illness and new approaches to its causes, diagnosis, treatment, prevention, and control. To achieve this goal, the NIMH funds extramural research programs through grants and contracts, and through intramural research operating through laboratories on the campuses of the National Institutes of Health and the grounds of St. Elizabeths hospital.

The 1981 budget places emphasis on five areas. First, there is a strengthening of research into the causes of major mental illnesses, notably schizophrenia and depression. Research projects build on recent discoveries relating to the role of behavioral, biological, and genetic factors in these illnesses and seek more active ways to select a proper treatment for these disorders.

Second, research concentrates on services delivery and the policies affecting these services, in order to better match populations in need of mental health care, health care financing, and the available resources of the service system. In addition, treatment assessment research will evaluate the appropriateness of various treatment modalities to ensure the development of additional and more reliable data on the incidence of mental illness.

Third, in furtherance of the recommendations of the President's Commission on Mental Health, there will be continued attention to the mental health needs of the underserved segments of the population.

Fourth, the Institute will support studies relating to the prevention of mental illness.

Fifth, the Institute will maintain its present research capability in all program areas.

National Institute on Drug Abuse

The Planning Process

NIDA has primary Federal responsibility for the initiation, development, and execution of a comprehensive research program in the field of drug abuse. Drug abuse research must not only focus on the precepts of good science guided by informed planning, but must also be sensitive to the ever-changing social scene with its concomitant demands for flexibility in relating research to the real world. The elements of scientific process and programmatic demand are integrated by NIDA's resource allocation strategy and program review mechanisms.

Central to the process of setting research priorities is the internal mechanism by which the Division of Research reviews and analyzes the program: current research findings and technical advances; progress of NIDA research grant and contract activities; epidemiologic data feeding in from national field surveys and State and local monitoring programs; and service utilization and program census statistics reported from local, State, and Federal agencies involved in drug abuse prevention and treatment programming.

A critical component of this research monitoring process is an objectives analysis system utilized by the Division of Research. The objectives analysis procedures is a four-level functional analysis of each research project. The aim is to specify both general scientific objectives of each project that directly relate to NIDA Research Program Goals and to provide an evaluation and feedback system for research planning. The system is meant to identify those research areas that have received sufficient or surplus efforts; to assist in identifying major areas in which greater emphasis on research is needed; and to indicate the nature and distribution of existing activities, the projected level of commitment, and the time lapse prior to expected outcome.

Programmatic priorities are also influenced by the advice coming from special one- or two-day gatherings of the foremost scientists in a field, from review of research results and program balance, and from epidemiologic data indicating the rise of special, unanticipated needs or trends in drug abuse. NIDA addresses these methods for determining research priorities by conducting technical reviews and conferences, analyzing research progress in specific subject areas using the Research Analysis Utilization System (RAUS), tracking research progress reports with the Drug Abuse Research Projects Information System (DARPIS), and collecting trend information on drug use through the National Survey of Drug Use, treatment utilization surveys such as CODAP, and other epidemiologic surveys. Gradually a consensus emerges regarding the most promising research directions, program relevance, and public perceptions of need.

Mission and Programs

The purpose of the NIDA research program is to develop knowledge in all aspects of drug abuse and addiction relevant to the development of effective treatment and prevention methodologies and to encourage the development of new technological approaches to the treatment and prevention of drug abuse and addiction.

The NIDA budget provides for the following areas of research focus: epidemiology, with special emphasis on adolescent use of "gateway" drugs and surveys of drug problems among the elderly, women, and native Americans; etiology, with an initiative on research on individuals who seem to be "immune" to drug abuse though living in the midst of an epidemic, and etiologic studies on basic mechanisms of withdrawal from nicotine addiction; hazards, with focus on the long-term health effects of marijuana use, especially by adolescents and women of reproductive age; prevention; treatment methodologies, with special emphasis on medication capable of blocking the effects of narcotics; basic research, with emphasis on research on endorphins; and treatment services research, with emphasis on family services, minority programs, women's programs, and evaluation models.

The special foci for intramural research include narcotic antagonists, health effects of marijuana on women, and development of new methodologies for determining the abuse potential of new drugs.

National Institute on Alcohol Abuse and Alcoholism

The Planning Process

Planning processes and priority setting within the NIAAA encompass several aspects of the research program: the development and structure of a national research capacity, the substantive content of the research program, and the internal management organization and capability within the Institute.

One of the primary bases of the planning efforts within the NIAAA has been the need to develop a national research capacity for the investigation of alcohol-related problems. This situation is unlike that in some fully developed

health fields that are seeking to maintain an existing capacity. Institute planning efforts therefore focus on the need for a national alcohol program that must include the stabilization and development of institutional research capability as well as of individual investigator competence, and must involve increased training capacity as well as attract both young investigators and already-established scientists now working in other fields.

The Institute uses workshops and conferences as means for identifying scientific questions of high priority in need of further research. In addition, collaborative programs with other institutes and agencies have been found to be valuable mechanisms for relating research to treatment and prevention programs. Such efforts serve to focus scientific attention on an area of importance and clarify the state of knowledge; to demonstrate the significance of alcohol to a number of other major health disorders and social problems; to attract and reach a pool of scientists or practitioners that would not normally be impacted by a research workshop that was purely alcohol-relevant; and to provide the basis for further program development.

Information on scientific opportunity and burden of illness and the identification of particular areas of importance are received by the Institute from a variety of sources, including various scientific groups, patient and professional constituent organizations, health practitioners, other government (Federal and non-Federal) programs, and Congressional committees. This input is obtained by the Institute through a variety of formal and informal processes, including staff contacts, correspondence, workshops and conferences, Congressional hearings and legislation, and formal program reviews sponsored by the Institute.

In addition to special workshops, the Institute has also sponsored reviews and reports that look at the alcohol research program from a broader perspective. A recent review of the management structure and capability of the research program within the institute resulted in an organizational and programmatic restructuring of the research components so as to enable the Institute program to better accomplish its objectives. Recommendations on various aspects of the national alcohol research program were included in the report of the President's Biomedical Research Panel (1976) and the reports of the President's Commission on Mental Health (1977-78) and its Research Task Force.

In addition, the Institute of Medicine, at the request of the NIAAA, has prepared a review of the alcohol field for the purpose of identifying the areas that seem to present the greatest opportunities for productive research. The NIAAA will use the results for the identification of further research directions.

The Institute is currently in the process of preparing a report to the Congress on the extent and nature of health hazards associated with the use of alcohol. This information will provide a useful basis for identifying areas of need and for development of future programs.

Mission and Programs

The long-range goal of the NIAAA research program is the development of new knowledge relevant to reducing the incidence and prevalence of alcohol abuse and alcoholism and to alleviating human suffering and death associated with alcohol.

Special areas of research interest include the following: etiology, with focus on efforts to identify the genetic and environmental factors of alcoholism; pathogenesis with expanded research on the effects of alcohol upon the brain and other organs; early identification; treatment, with focus on the development of treatment techniques and assessment methods and on subtypes of alcohol problems and alcoholic patients; prevention, including development of techniques to reduce alcohol-related accidents and violence; basic research, including support for development of improved animal models of alcoholism and studies of the genetic bases of alcoholism; and intramural research, with special focus on health problems that result from alcohol use, including the relationship of alcohol consumption to cancer and heart disease.

FY 1981 Budget
(In Thousands)

I. Total Budget--Summary

NIMH	$ 658,346
NIDA	238,284
NIAAA	150,111
Program Management	10,867
Buildings and Facilities	5,425
Subtotal	1,063,033
St. Elizabeths	94,273
SEH Building/Facilities	1,500
HHS Health Research Initiatives:	
Stabilizing the Science Base	(139,500)
Population	(10,659)
Smoking and Health	(3,200)
Alzheimer's Disease	(5,100)
Nutrition	(5,429)
The Individual Consumer in Health	(9,760)
Total	$1,158,806

Alcohol, Drug Abuse, and Mental Health Administration

II. Research--by Mechanism (In Thousands)

NIMH:	
Regular research grants	$ 102,397
Research centers	6,500
RSDA	5,171
Research contracts	4,580
Intramural Research	37,771
Total	$ 156,419*
NIDA:	
Regular research grants	$ 30,816
Research centers	2,983
RSDA	1,034
Research contracts	8,871
Intramural Research	4,263
Total	$ 47,967**
NIAAA:	
Regular research grants	$ 11,598
Research centers	7,250
RSDA	1,426
Research contracts	390
Intramural research	4,017
Total	$ 24,681***

* Excludes $6,000 thousand now associated with prevention programs.
** Excludes $2,300 thousand now associated with prevention programs.
***Excludes $460 thousand now associated with prevention programs.

III. Research--by Program Area (In Thousands)

NIMH:	
Extramural:	
Behavioral	$ 16,312
Clinical	17,156
Applied	7,954
Psychopharmacology	16,382
Aging	5,320
Epidemiology	6,499
Services	14,015
Crime & Delinquency	5,447
Metro. Problems	3,502
Minority M.H.	6,310
Rape	4,218
Research Scientist	5,171
Research Centers	6,500
Small Grants	2,300
Other	1,562
Subtotal	$118,648
Intramural:	
Clinical and Behavioral	11,340
Biological and Biochemical	5,965
Special Mental Health Research	6,165
Subtotal	23,470
NIH Management Fund	14,301
Subtotal	37,771
Total, NIMH	$156,419

Alcohol, Drug Abuse, and Mental Health Administration

NIDA:	(In Thousands)
Extramural:	
Epidemiology	$ 2,500
Etiology	2,500
Hazards	5,400
Treatment Methodologies	7,100
Treatment Services	3,000
Basic	16,904
Research Support	6,300
Subtotal	43,704
Intramural:	
Clinical Pharmacology	1,820
Animal Pharmacology	960
Chemical Pharmacology	550
Neurosciences	650
Psychosocial	208
Subtotal	4,188
NIH	75
Subtotal	4,263
Total, NIDA	$ 47,967

NIAAA:	(In Thousands)
Extramural:	
Etiology	$ 5,460
Pathogenesis	9,856
Early Identification	1,066
Treatment	2,784
Basic Tools and Methodologies	1,498
Subtotal	20,664
Intramural:	
Clinical Investigations	$ 206
Epidemiology	1,719
Metabolism Research	1,056
Preclinical Studies	1,036
Subtotal	4,017
Total, NIAAA	$24,681

Alcohol, Drug Abuse, and Mental Health Administration

A Selection of Recent Major Planning Reports of the Alcohol, Drug Abuse, and Mental Health Administration

ADAMHA--General

Five-Year Research Plan

National Institute on Drug Abuse

Issues in Controlled Substance Use, 1980
Research on Smoking Behavior, 1977
Review of Inhalants: Euphoria to Dysfunction, 1977
Behavioral Tolerance: Research and Treatment Implications, 1978

National Institute of Mental Health

The Older Woman: Continuities and Discontinuities--Report of the NIA and NIMH Workshop, October 1979
Proceedings of the NIMH Workshop on the Hyperkinetic Behavior Syndrome, 1979
Women and Psychotherapy: Priorities for Research, 1979
Issues in Mental Health an Aging, Volume I, Research, 1979
Research in the Service of Mental Health: Report of the Research Task Force of the NIMH, 1975
Important Areas for Children's Mental Health Services Development, 1978
Research Directions for Rural Mental Health, July 1979

National Institute on Alcohol Abuse and Alcoholism

Report of the Workshop on Alcohol and Cancer--Cosponsored by the National Cancer Institute and the National Institute on Alcohol Abuse and Alcoholism, July 1979
Report of the Workshop on Nutrition, April 1980
Report of the Workshop on Alcohol and Women, May 1980
Report of a Symposium on Normative Approaches to the Prevention of Alcohol Abuse and Alcoholism, June 1980
Report of the Workshop on Alcohol and the Workplace (in press)
Report of the Workshop on Evaluation of the Alcoholic: Implications for Research, Theory and Treatment (in press)
Report of the Task Panel on Alcohol-Related Problems of the President's Commission on Mental Health, 1978
Report of the Institute on Medicine/National Academy of Science on Scientific Opportunities in Alcohol-Related Research Areas (available July 1980)

Chapter 3

CENTER FOR DISEASE CONTROL

Agency head:

Dr. William H. Foege
Director
Center for Disease Control
Building 1, Room 2104
1600 Clifton Road, N.E.
Atlanta, Georgia 30333
(404) 236-3291

Planning contact:

Mr. Norman Axnick
Director, Office of Program Planning
and Evaluation
Office of Center Director
Building 1, Room 2035
1600 Clifton Road, N.E.
Atlanta, Georgia 30333
(404) 236-3243

Budget contact:

Mr. Claude F. Pickelsimer, Jr.
Director, Financial Management Office
Office of Administrative Management
1600 Clifton Road, N.E.
Atlanta, Georgia 30333
(404) 262-6600

Chapter 3

CENTER FOR DISEASE CONTROL

The Planning Process

Health research planning and priority-setting are integrated with the program planning effort for the CDC service-oriented mission. CDC research efforts are planned to contribute to critical needs for prevention of disease, disability, and death associated with environmental and workplace hazards, prevention and control of infectious and chronic diseases, and promotion of health.

The current planning effort reflects the recently completed external review. Two years ago the Director of CDC initiated a project to plan how CDC can best work toward its service mission. The first phase was the participation of outside groups and individuals as to recommendations of what CDC's programs should be to achieve the goal of preventing or reducing unnecessary morbidity and mortality in the United States. Several hundred organizations and individuals responded. The second phase was the recommendations on CDC's future programs by an advisory group of outside persons. This group was asked to examine current trends in morbidity and mortality in the United States, to evaluate problems according to the impact that program interventions would have on reducing unnecessary morbidity and mortality, and, on the basis of that impact, to classify problems as to priority. These priority recommendations are reflected in the current planning effort with respect to the overall strategy and priority setting.

Since the National Institute for Occupational Safety and Health (NIOSH) serves as the research component of the Federal Occupational Safety and Health program, a brief description of the Institute's health research planning during its eight-year history is presented.

In responding to the Occupational Safety and Health Act of 1970, NIOSH began by using a simple system of priority-setting. To pick research issues, it looked at single agents by relative toxicity judged subjectively and at the number of workers exposed. This research agenda was focused on as complete an evaluation of each agent as possible, which was closely tied to the development of criteria documents usually dealing with single agents.

Current System. However, to assure more and better use of NIOSH results, a more sophisticated priority and planning system was required. The new system is better suited to the needs of NIOSH and can assure that the agency reaches those who need the research results, but it still lacks the precision that would be available from a national reporting and surveillance system for occupational disease, disability, and mortality.

The framework of the current Institute management plan to establish priorities for the identification, evaluation, and control of occupational hazards includes the following major components:

National Occupational Hazard Survey:

- Identifies the chemicals found in a representative sample of workplaces, and describes occupational safety and health programs there. Used to estimate potential worker exposure.

- Basic source of in-vitro and animal testing data, and the link to the Toxic Substances Control Act data base. Used to acquire new toxicity data.

Health Hazard Evaluations:

- NIOSH on-site investigations of workplaces in response to worker, employer, and government agency requests. Includes both industrial hygiene and medical evaluations. Used to find new problems and to evaluate their significance.

Industry-Wide Studies:

- NIOSH research to define the hazards of an industry or a particular agent. Large worker cohorts are usually studied. These results become part of the estimates of health effects used in the NIOSH management system.

Control Technology Assessments:

- NIOSH research projects to define the effective engineering controls that exist or could be developed. These results are used to choose particularly productive study areas.

DOL/NIOSH Planning Group:

- An organized effort by the Department of Labor to request research results from NIOSH. This prioritized list provides NIOSH with the needs of the two regulatory agencies served by statute--Occupational Safety and Health Administration (OSHA) and Mining Safety Health Administration (MSHA).

The major output of the management system is an annual plan comprising about 325 continuing and new projects. Establishment of new priorities for NIOSH has led directly to significant shifting of its resources. Additional person-years have been redirected from support functions to field activities, and funds have been redirected to provide these support functions. These shifts are only the first steps in a continuing effort to expand epidemiologic studies and to improve the dissemination of findings of occupational health and safety.

Mission and Programs

The mission of the Center for Disease Control is to prevent unnecessary morbidity and mortality by assisting State and local health authorities and other health-related organizations in stemming the spread of communicable diseases; protecting against other diseases or conditions; providing protection from certain environmental hazards; and improving occupational health and safety.

CDC accomplishes this mission through a multifaceted program:

- Basic preventive health activities--health incentive grants, disease-risk-reduction demonstrations, and health education;
- Targeted disease prevention programs to States and communities--venereal disease control, childhood disease immunization programs, influenza immunization programs, fluoridation programs, control of infectious and chronic diseases, and prevention of environmental hazards such as lead-based paint poisoning;
- Backstopping States with epidemic investigations and toxic emergency assistance;
- Promotion of occupational safety and health;
- Laboratory services and improvements; and
- International health cooperation.

To carry out these programs, CDC is organized into eight components--the National Institute for Occupational Safety and Health and the Bureaus of Epidemiology, Health Education, Laboratories, Smallpox Eradication, State Services, Training, and Tropical Diseases.

CDC's headquarters adjoin Emory University in Atlanta, Georgia. They include a core of laboratories, offices, and specialized training facilities. The Bureau of Epidemiology has field installations in Anchorage, Alaska, and Phoenix, Arizona. The Bureau of Laboratories has field facilities in Fort Collins, Colorado, Lawrenceville, Georgia (Animal Center), and San Juan, Puerto Rica; and the Bureau of Tropical Diseases has a research station in San Salvador, El Salvador.

Headquarters for NIOSH are in Rockville, Maryland, with laboratories in Cincinnati, Ohio, and Morgantown, West Virginia.

CDC employs about 4,000 persons. Among these are biologists, behavioral scientists, chemists, dentists, education specialists, entomologists, engineers, industrial hygienists, epidemiologists, physicians, nurses, public health advisors, statisticians, toxicologists, and veterinarians--to name a few of the 165 occupations represented. Almost half of the staff is located in the Atlanta area. In addition to those assigned to Federal installations--

laboratories, field stations, and foreign quarantine stations--others are working at State and local health agencies.

CDC sponsors a wide spectrum of research--laboratory, epidemiologic, behavioral, health service--in support of its service mission. About 34 percent of the agency's $293 million budget is allocated for this purpose. For fiscal year 1981, the CDC budget includes $100.4 million for research supportive of CDC's preventive mission--$22.1 million for disease control, $6.6 million for health education, and $71.7 million* for occupational safety and health. In addition, CDC carries out some international research, with support from AID, WHO, and PAHO.

In the disease control area, CDC sponsors research into problems identified in epidemiologic investigations, diagnostic services, and implementation of national disease control programs. For example, the Legionnaire's disease outbreaks required research to complete the epidemiologic and laboratory work with respect to disease definition.

In the health education area, CDC supports behavioral and health service research related to patient education, improvement of school curricula for health education, sex education, nutrition education, and other needs.

To assure safe and healthful working conditions for all working people, occupational safety and health standards are developed, and research and other activities carried out, through the Center's National Institute for Occupational Safety and Health (NIOSH). For fiscal year 1981 the NIOSH research program will receive $58.5 million. Its major activities include:

- Laboratory and field research on hazards from such physical agents as noise, vibration, heat, and nonionizing and ionizing energy sources;
- laboratory and worksite research on the physiological effects of occupational environments and stresses;
- Laboratory and field research on the psychological, motivational, and behavioral factors involved in occupational safety and health;
- Epidemiologic studies on the incidence and prevalence of acute and chronic disease in the working population and their offspring and on the nature and extent of actue and chronic responses to potentially hazardous agents in the work environment;
- Epidemiologic studies to determine specific cause-and-effect relationships between the interaction of human behavior, environmental factors, and the causative agents of accidents or injuries;
- Industrial hygiene studies to characterize and quantify physical, biological, and chemical agents to which the working population is exposed;
- Laboratory and worksite research to assess and develop engineering control techniques to prevent exposure to toxic substances and harmful physical agents;

*Includes science base, technology transfer, and training.

- Equipment development, analytical and sampling methods development, and equipment calibration for the measurement and control of occupational health hazards; and
- Laboratory research to develop critical toxicity data produced by acute, subchronic, and chronic exposures to etiologic agents encountered in the occupational environment, and to investigate mechanisms of occupational disease causation.

FY 1981 Budget for the Agency
(In Thousands)

	Total	Research	Percent
Occupational safety and health	$ 81,200	$ 71,654*	88.2%
Disease Control	198,500	22,100	11.1%
Health education	13,700	6,600	48.2%
Total	$293,400	$100,354	34.2%

*Includes science base, technology transfer, and training.

Center for Disease Control

FY 1981 Budget for Research
(In Thousands)

Extramural:	
Research grants	$ 5,754
Research training	--
Contracts	28,700
Other	12,900
Subtotal	47,354
Intramural:	53,000
HHS Health Research Initiatives:	
National Toxicology Program	(5,100)
Effects of Radiation	(1,600)
Population	(250)
Smoking and Health	(2,000)
Nutrition	(240)
Prevention of Occupational Disease	(4,416)
Prevention of Reproductive Effects	(2,849)
Accelerated Development of New Vaccines	(608)
Other	--
Total	$100,354

Center for Disease Control

A Selection of Recent Major Planning Reports of the Center for Disease Control

Office of the CDC Director

Recommendations of a National Strategy--CDC Programs and Policies Advisory Committee, June 1978
Prevention Objectives for the Nation, August 1979
Model Standards for Community Preventive Services, August 1979

National Institute for Occupational Safety and Health

NIOSH Program Plan, Fiscal Year 1980

Chapter 4

FOOD AND DRUG ADMINISTRATION

Agency head:

Dr. Jere E. Goyan
Commissioner of Food and Drugs
HF-1
5600 Fishers Lane
Rockville, Maryland 20857
(301) 443-2410

Planning contact:

Dr. Constantine Zervos
Director, Scientific Liaison and
Intelligence Staff
Food and Drug Administration
HFY-31
5600 Fishers Lane
Rockville, Maryland 20857
(301) 443-4490

Budget contact:

Mr. Frank Claunts
Director, Division of Financial Management
Food and Drug Administration
HFA-100
5600 Fishers Lane
Rockville, Maryland 20857
(301) 443-3260

Chapter 4

FOOD AND DRUG ADMINISTRATION

Bureau Research Planning

In 1970 the Food and Drug Administration (FDA) established a Program Management System (PMS) built around major agency responsibilities (e.g., food safety, human drugs, medical devices) rather than according to traditional line authority structures. The reason for the PMS is the need for effective utilization of limited resources. Planning for research activity is done primarily within the context of the PMS.

Each program of the PMS comprises a circumscribed cluster of related activities of the agency and the specific Bureau. One of the activities of each program is the research necessary to conduct the other activities in a scientifically sound manner. Each program of the PMS is under the control of a program manager who is responsible for the strategies and activities that will further the program's goals. Thus, research ideas and projects originate with program personnel and are first evaluated by the program managers. Beyond that, the research plans of the FDA Bureaus do not receive independent review and evaluation as an aggregate agency-wide activity. Instead, they are reviewed and evaluated as parts of the PMS.

Each program manager prepares and presents his plans for all program activities two years in advance, with alternative levels of funding. Strategies and planned activities are first presented to the Bureau and then the agency management. Programs are reviewed periodically by the Commissioner and his staff. Program research activities are also reviewed in the context of overall program goals and problems.

Priority-setting occurs within the PMS process and is based upon the following two criteria:

- Remaining Risk: the real loss of injury experienced by the public--i.e., the remaining problem or hazard to be eliminated.

- Public Concern: intensity of interest as expressed by consumers, the Congress, the Administration, and industry. High public concern is typically engendered by high consumer vulnerability and lack of product substitutes.

Clearly these factors are dependent upon the needs of the moment. In an era of limited funds, a need for inspection or compliance could displace a well-planned research project.

Mission and Programs

The programs of FDA are designed to achieve a single overall objective: consumer protection. FDA's mission is to ensure that--

- Food is safe, pure, and wholesome;
- Human and animal drugs, biological products, and therapeutic devices are safe and effective;
- Radiological products and procedures do not result in unnecessary exposure to radiation; and
- Products are honestly labeled.

To accomplish its mission, FDA sets food and product standards; evaluates the safety and efficacy of new drugs before they are marketed; conducts and sponsors research to detect health hazards and violations of consumer laws or regulations; informs business firms and consumers about FDA-related topics; works with State and local agencies to develop programs that will supplement or complement those of FDA; ensures that products are safe, effective, and honestly labeled; and takes legal action where necessary to remove violative products from the marketplace and to prosecute firms or individuals that violate the law.

Most FDA regulatory actions require information generated through laboratory research and through evaluations conducted by well-trained, well-informed agency scientists. Regulatory actions of the FDA reflect some of the most important public health decisions made in the Federal Government, and many such actions can redirect the flow of capital from one particular product or area to another. Scientific research is, therefore, important for both the general improvement of regulatory decision-making and as a key national resource when serious health problems require special attention. Indeed, the degree to which regulatory decisions gain credibility and merit the support of the public and the scientific community depends on the extent to which they reflect the best available scientific knowledge.

FDA employs 7,623 persons. They are distributed among the six Bureaus, the National Center for Toxicological Research (NCTR), and the regional operations that constitute the agency. Approximately 1,000 man-years are devoted to intramural research in the constituent Bureaus, and some $17.5 million is expended for contracted extramural research. A great portion of the extramural research is conducted in universities throughout the country.

The Bureaus are dispersed geographically. The laboratories of the Bureau of Foods and the Bureau of Drugs are located in Washington, D.C.; the Bureau of Radiological Health has laboratories in Rockville, Md.; the Bureau of Veterinary Medicine has laboratories in Beltsville, Md.; the Bureau of Biologics is on the NIH campus in Bethesda, Md.; and the Bureau of Medical Devices is in Silver Spring, Md., with laboratories in the Department of Agriculture building in Washington, D.C. The National Center for Toxicological Research is in Jefferson, Ark.

The Office of the Commissioner and the administrative offices are located in the Parklawn Building, Rockville, Md., as is the Executive Office for Regional Operations (EDRO), from which testing activities are directed in laboratories in New York, San Francisco, Los Angeles, Denver, Baltimore, Boston, Seattle, Cincinnati, Philadelphia, Atlanta, Chicago, Detroit, Minneapolis, Dallas, New Orleans, and Kansas City.

The agency's research budget of approximately $64 million in 1980 constitutes about 20 percent of the total agency budget. $66 million is projected for fiscal year 1981.

The National Center for Toxicological Research

Unlike the other FDA Bureaus, the NCTR has no line responsibilities. Its exclusive mission is to conduct research in support of regulation. Planning for research is targeted to the Center's mission statement, which is to conduct studies on the biological effects of potentially toxic chemical substances found in man's environment, emphasizing--

- The determination of the health effects that result from long-term, low-level exposure to chemical toxicants;
- Understanding of the basic biological processes of chemical toxicity in animals and man;
- The development of improved methodologies and test protocols for evaluating the safety of chemical toxicants; and
- The gathering of data that will facilitate the inferences of toxicological risks from laboratory animals to man.

At the NCTR, general research direction is given by a policy board consisting of the Commissioner of the Food and Drugs, the Administrator of the Environmental Protection Agency, and three additional delegates from each of these two agencies.

The responsibility for research planning is shared by the Director, the Associate Directors, and the Division Directors. Research projects are suggested by NCTR staff, FDA Bureaus, EPA, CPSC staffs, and the National Toxicology Program staff. The Science Advisory Board (consisting of non-NCTR scientists) and the Research Scientists Group (consisting of NCTR scientists) review the protocols for suggested studies. The protocols are also reviewed by interested agencies or bureaus. The progress of approved projects is reviewed by the Science Advisory Boards and its subcommittee as well as by the Director and Associate Directors.

FY 1981 Health Research Plan

As discussed in the introduction to this volume and in the FDA section of

the preceding volume, "Current Efforts and Proposed Initiatives," FDA's research efforts are tied to the regulatory information needs of the agency. Thus, year-to-year changes in emphasis are not dramatic--as, indeed, one would hope, given a reasonably foresightful research plan. Some areas that will receive increasing attention this year are based upon:

The Individual's Responsibility for Health Care

A number of recent events and trends have made it clear that many of the country's health care and health regulation problems can only be solved if individual consumers take a more active role in their own health care. The saccharin and Laetrile controversies indicate that many individuals do not want the government to make some health decisions for them. Increasing support for patient labeling and increased interest in food labeling indicate that people are concerned and are both willing and capable of participating in decisions about the food and drug products they consume. A number of FDA activities have progressed to a point where it will soon be possible for the agency to initiate a comprehensive effort in these areas to provide consumers with the facts they need to make informed health decisions. This comprehensive effort will involve:

- An expanded program of patient package insert labeling (PPI);
- Accelerated implementation of over-the-counter drug evaluation findings;
- A comprehensive food labeling effort, involving both nutritional and ingredient labeling;
- Continued efforts to ensure safe and effective medical devices; and
- Continued efforts to inform consumers of potential health risks associated with cosmetic usage.

The foregoing areas of emphasis are not those requiring basic health research, though they do have informational research content. Because FDA's planned research activities are contained within each element of the 9 program areas and 45 projects of the PMS, it is not practical to summarize them for this document. Many were described in "Current Efforts and Proposed Initiatives." These that cut across PMS lines, however, are included here for your convenience. The general problems, goals, and approaches brought out in those summaries are broad and recurrent ones. Whenever budgetary resources become available, research into these areas will be initiated.

Research Activities--Overview

Insofar as health research is devoted to increasing knowledge about the human health risks associated with specific substances, it provides the primary basis for FDA's public health protection role. However, health research that is concerned with the underlying mechanisms of diseases that may result

from human exposure to toxic chemicals, biological products, or radiation is of even greater importance to the regulatory process. Such research contributes to improving the assessment of human health risks and thus assures that regulatory decisions are directed toward substances having the greatest impact on public health. Research designed to relate observations in experimental systems with human experience is of fundamental importance to regulation.

FDA has for many years provided scientific leadership in the development of methods to detect and measure substances that affect the safety of foods, drugs, cosmetics, radiological products, and other substances coming under its authorities. Such measurements are of crucial importance in public health protection. Significant accomplishments have been in the areas of multiresidue methodology for pesticides, industrial pollutants, naturally occurring toxicants (such as aflatoxins), drugs, radiation-emitting devices, biological products, and microbial contaminants. Development of toxicity data on such substances has contributed to greater understanding of their roles in human disease.

FDA has played a prime role in the development of the whole field of mycotoxicology. Research at the agency's National Center for Toxicological Research has deepened understanding of the nature of the dose-response relationship in carcinogenesis experiments. The agency has also had a fundamental role in the development of new knowledge about the health hazards associated with various forms of ionizing and nonionizing radiation and with biological products such as vaccines.

Basic Toxicology Research

FDA is mandated by the Congress to provide premarketing clearance for new human drugs, animal drugs, food additives (direct or indirect), and medical devices. In all cases, the agency must assure that these agents are used safely and are efficacious for their intended uses. Most of the areas of toxicology research are associated with foods and cosmetics.

The studies encompass acute and subchronic, teratological, behavioral, immunotoxicological, neurophysiological, metabolic biochemical, neonatal, genetic, dermal, and ocular investigative activities. The extramural research programs are an extension of the intramural activities and consist essentially of mission-oriented applied research related to drugs, cosmetics, food additives, and food contaminants.

The role of the National Center for Toxicological Research in the support of toxicology research, testing, and method development is to gain a better understanding of adverse health effects of potentially toxic chemicals on living organisms, with particular emphasis on determining the adverse health effects resulting from long-term, low-level exposure to chemical toxicants (food additives, residues or animal drugs, etc.); determining the basic biological processes involving chemical toxicants in animal organisms in order to permit better extrapolation of toxicological data from laboratory animals to man; and developing improved methodologies and test protocols for evaluation of the safety of chemical toxicants (good laboratory practices, automated data systems, etc.).

Toxicology Method Development

The purpose of toxicology method development at FDA is to develop and validate procedures that are faster and more economical, reliable, and meaningful for extrapolation to man. Methods that significantly meet any one of the established conditions are worthy of consideration. The ultimate goal is short-term *in vitro* tests for safety evaluation to replace the present chronic studies in animals, which are expensive and time-consuming.

The programs in method development currently span the areas of dermal toxicity, mutagenesis, behavioral toxicity, drug toxicity, immunotoxicology, and studies of biochemical indices of toxicity. Current emphasis is on short-term intensive studies in animals to obtain a base of diverse data that may be indicative of long-term effects. Many method-related studies also test chemicals not previously evaluated and are therefore listed under the testing program. Eventually, known toxic, mutagenic, or carcinogenic substances will be used in studies to predict their long-term effects.

A portion of some of the metabolic studies could be classified as basic research, but since the prime thrust is methodology development, they are so listed. Examples are biochemical parameters of toxicology, intermediary metabolism, macromolecular biosynthesis, and lipid metabolism.

There are a number of drug-related research projects directed toward toxicology method development. These include construction of electrocardiographic models, their correlation with histopathological findings, and the development of animal models for--

- Detecting potential drug-induced organ toxicity,
- Predicting diseases,
- Comparing hyperimmunologic responses,
- Testing teratogenesis and other birth defects, and
- Investigating antidotal therapy.

Food and Drug Administration

FY 1981 Budget
(In Thousands)

Research	Amount	Percent of Total
Extramural:		
Research grants	$ 1,868	
Research training	--	
Contracts	15,925	
Other	--	
Subtotal	$ 17,793	5.5%
Intramural	48,419	
Research total	$ 66,212	20.5%
HHS Health Research Initiatives:		
National Toxicology Program	(6,790)	
Effects of Radiation	(5,700)	
Population	(155)	
Nutrition	(4,690)	
Prevention of Reproductive Effects	(3,224)	
The Individual Consumer in Health	(1,700)	
Accelerated Development of New Vaccines	(4,800)	
Other	256,458	79.5%
Total	$322,670	

Research Planning Documents of the Food and Drug Administration

A Model for Research Planning in the Food and Drug Administration (1978)

This task force-generated report delineates the steps necessary for the development of research projects of definite and readily identifiable value to the specific mission requirements of FDA. It constitutes a research planning model and incorporates stages ranging from agency policy-making to the work of experimental scientists.

Bureau of Food Research Plan (1980)

This document outlines the extensive range of possible research projects that would come within the mission of the Bureau of Foods. These documented needs, which would contribute to the Bureau's technical ability to evaluate and control food safety, are for the most part unapproachable at the desired depth because of budgetary limitations. Thus, while the Research Plan clearly aids in orienting the Bureau of Foods research, its major value may come from needs seen and addressed by other agencies or by generating the additional and necessary support.

Bureau of Medical Devices Research Plan (1980)

This is a concerted attempt to define the research and basic science needs of this relatively new Bureau vis-a-vis the health community, the medical device industry, and of course its specific mission. It develops the reasoning behind the need for BMD research, enumerates goals and specific projects, and suggests mechanisms for implementation and oversight.

FY 1981 PMS Blue Book

This book abstracts all 45 PMS projects and lists project contacts within the nine program areas of the Program Management System (PMS). It is published as a reference for PMS managers as well as to encourage feedback and interaction throughout the agency.

Chapter 5

OFFICE OF HEALTH RESEARCH, STATISTICS, AND TECHNOLOGY

Agency head:

Mrs. Ruth S. Hanft
Deputy Assistant Secretary
for Health Research,
Statistics, and Technology
Parklawn Building, Room 17A-55
5600 Fishers Lane
Rockville, Md. 20857
(301) 443-2790

Planning contacts:

Dr. Joel Kavet
Associate Director for
Program Development
Parklawn Building, Room 17A-55
5600 Fishers Lane
Rockville, Maryland 20857
(301) 443-1927

Dr. Samuel P. Korper
Associate Director for
Legislation, Epidemiology,
and the Environment
Parklawn Building, Room 17A-55
5600 Fishers Lane
Rockville, Md. 20857
(301) 443-2660

National Center for Health Care Technology

Agency head:

Dr. Seymour Perry
Director
National Center for Health
Care Technology
Parklawn Building, Room 17A32
5600 Fishers Lane
Rockville, Maryland 20857
(301) 443-4097

Planning contact:

Mr. John Rodak, Jr.
Associate Director for Planning,
Evaluation, and Legislation
Parklawn Building, Room 17A29
5600 Fishers Lane
Rockville, Md. 20857
(301) 443-1610

Office of Health Research, Statistics, and Technology

National Center for Health Services Research

Agency heads:

Dr. Gerald Rosenthal
Director
National Center for Health
Services Research
Federal Center Building #2, Room 8-41
3700 East-West Highway
Hyattsville, Maryland 20782
(301) 436-6944

Dr. Barbara McCool
Deputy Director
National Center for Health
Services Research
Federal Center Building #2, Room 8-41
3700 East-West Highway
Hyattsville, Maryland 20782
(301) 436-6944

Planning contacts:

Dr. Donald Goldstone
Associate Deputy Director for Medical
and Scientific Affairs
Federal Center Building #2, Room 841
3700 East-West Highway
Hyattsville, Maryland 20782
(301) 436-6947

Dr. Ira Raskin
Director
Office of Program Development
Federal Center Building #2, Room 850
3700 East-West Highway
Hyattsville, Md. 20782
(301) 436-8920

Chapter 5

OFFICE OF HEALTH RESEARCH, STATISTICS, AND TECHNOLOGY

The Office of Health Research, Statistics, and Technology (OHRST) serves as the principal advisor to the Assistant Secretary for Health on matters concerning health services research and health care technology, as well as the statistical activities authorized by Sections 304-309 of the Public Health Service Act (42 U.S.C. 201 and 42 U.S.C. 242). In carrying out these responsibilities, the OHRST--

- Conducts a national program of health services research, evaluation, demonstration, and health services research training;
- Collects, analyzes, and disseminates data on vital and health statistics, health status, health resources assessment, the utilization, organization, and management of health services, health expenditures, environmental health, and related matters; and
- Conducts a national program of health care technology assessment, research, demonstration, evaluation, and health care technology training.

In order to carry out this mission, OHRST provides programmatic oversight, policy planning, administrative support, and coordination of the activities of the National Center for Health Care Technology (NCHCT), the National Center for Health Services Research (NCHSR), and the National Center for Health Statistics (NCHS). In addition, the office is responsible for coordinating issues of statistical and health services research with programs within the Public Health Service and between PHS and the Health Care Financing Administration.

The research planning processes that guide the formulation and conduct of research programs in NCHSR and NCHCT have been tailored to the responsibilities and needs of each Center and are discussed in the following sections.

National Center for Health Care Technology

The NCHCT, or the Center, is mandated to conduct and support a range of research, demonstration, and evaluation activities related to health care technologies. The programs of the Center are planned and operated in a way that reflects the NCHCT's recognition of its responsibility to serve as the focal point for conducting and coordinating health care technology assessments within the Department.

Office of Health Research, Statistics, and Technology

The Center's program planning decisions are influenced by the deliberations of the Department's Technology Coordinating Committee (TCC). The TCC, composed of representatives from all the PHS agencies and the Health Care Financing Administration (HCFA), serves as a forum where Departmental matters related to health care technology are addressed. The following HHS offices and agencies are members:

Office of the Secretary

Office of the General Counsel

Office of the Assistant Secretary for Health

Office of Health Research, Statistics, and Technology (OHRST):

National Center for Health Care Technology
National Center for Health Services Research
National Center for Health Statistics

National Institutes of Health

Alcohol, Drug Abuse, and Mental Health Administration

Center for Disease Control

Food and Drug Administration

Health Care Financing Administration

Health Services Administration

Health Resources Administration

Other Federal departments, agencies, and offices with an interest in health care technology are also represented on the TCC. These include, for example, the National Institute of Handicapped Research, Department of Education; the Office of Science and Technology Policy, Executive Office of the President; the congressional Office of Technology Assessment; the Veterans Administration; and the Department of Energy. Other Federal agencies, such as the National Aeronautics and Space Administration and the National Bureau of Standards, may also be invited to participate in the TCC as appropriate.

A second significant source of guidance to the Center is the National Council on Health Care Technology (Council), which by law advises the Secretary and the Director of the Center. The Council contributes to the Center's priority-setting activities by identifying particular health care technologies for the Center's assessment program, and also fulfills review and advisory functions in conjunction with the Center's grant program.

The Center's program planning and priority processes also reflect attention to concerns voiced by the Office of the Secretary and the Office of the

Assistant Secretary for Health and to issues raised by the Health Care Financing Administration (HCFA) concerning Medicare coverage of particular technologies.

The major emphases of the research programs of the NCHCT in FY 1981 are to be:

(1) Development and testing of methodologies for assessing the safety, efficacy, and effectiveness of particular health care technologies and their social, economic, and ethical impacts.

The current state-of-the-art of health care technology assessment is limited by conceptual, methodological, and data problems that constrain the production of useful evaluative information. Hence, efforts will be directed toward developing and defining methodologies that have potential for widespread application.

Examples of the areas where emphasis will be placed include:

- Methods for assessing rapidly changing technologies;
- Measures of effectiveness, risk, benefit, and cost;
- Economic evaluation of diagnostic procedures;
- Short-term outcome measures in evaluating therapeutic effectiveness;
- Improved methods of using existing data sources for technology assessment;
- Strategies for information retrieval applicable to technology assessment.

(2) Assessments of limited scope which involve analyses of specific aspects of a technology (e.g., its safety, efficacy, effectiveness, or social, ethical, or economic implications). These studies will focus on those aspects of a technology for which in-depth assessments or analyses are particularly essential for health care policy decisionmaking.

The following list of priority candidate topics for technology assessments was developed by the NCHCT, based on recommendations from its advisory bodies. The list illustrates the types of topics to which the Center will be devoting attention in the coming years. (An asterisk before the item indicates a high-priority technology, with assessment recommended by the Council.)

*Maternal serum alpha-fetoprotein (MSAFP) test for detection of fetal neural tube defects[1]

*Coronary artery bypass surgery[2]

*Total knee replacement

*Total hip replacement

*Ultrasound for cardiac diagnosis

*Cerebral artery bypass surgery for treatment of stroke

*Positron emission transaxial tomography (PETT)

*Dental X-rays

*Cesarean section and electronic fetal monitoring[3]

*Renal transplant and dialysis for end-stage renal disease (ESRD)

*Heart transplants

Computerized tomographic (CT) scanning of the head and body

Cardiac nuclear imaging

Barium enema

Skull X-rays

Total parenteral nutrition

---

1. The NCHCT and the Food and Drug Administration (FDA) cosponsored a national educational conference, "MSAFP: Issues in the Prenatal Screening and Diagnosis of Neural Tube Defects", in July 1980.

2. The National Heart, Lung, and Blood Institute (NHLBI), NIH, in conjunction with the NCHCT, held a consensus development conference on coronary artery bypass surgery (medical and scientific aspects) on December 3-5, 1980. The NCHCT, in conjunction with the NHLBI/NIH, will convene a national conference on the social, economic, and ethical aspects of coronary artery bypass surgery in April 1981.

3. The National Institute of Child Health and Human Development (NICHD), NIH, held in September 1980, in conjunction with the NCHCT, a consensus development conference on cesarean delivery.

Pap test in cervical cancer screening[4]

Endoscopy in upper GI hemorrhage[5]

Psychotherapeutic techniques

Nuclear magnetic resonance

Electroencephalography

Neonatal intensive care units

Neurosurgery for mental disorders

Continuous flow analysis/multianalyses

In FY 1981, NCHCT will allocate $3.4 million to the support of its technology research activities.

National Center for Health Services Research

The Planning Process

Since its establishment, the National Center for Health Services Research (NCHSR) has been committed to the development of a planning process to ensure that feasible research projects of potentially high social utility are incorporated into the Center's research effort. The NCHSR believes that such planning is essential to a productive research program.

A crucial step in the formulation of a health services research program is the identification of those subject areas that ought to be given priority when the decisions are made about which research projects to support. In general, problems that affect the allocation of substantial resources, which in turn affect the health of a large segment of the population or command growing legislative interest, would seem to be obvious candidates. Yet, there is no widely accepted scheme for weighting and ordering in terms of relative importance the myriad of health care problems that, from time to time, attract the attention of the public as well as those in the field itself.

4. The National Cancer Institute (NCI), National Institute on Aging (NIA), and the NICHD, NIH, held in July 1980 a consensus development conference on the PAP smear in cervical cancer screening; NCHCT supported a speaker who presented an economic analysis.

5. The National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMDD), NIH, held a consensus development conference in August 1980 on endoscopy in upper GI hemorrhage. The NCHCT supported a speaker who presented an economic analysis.

To deal with this situation, the NCHSR regularly calls upon policy-makers, consumers, health care providers, and program administrators to identify the current and emerging health care issues which they believe to be most pressing. The NCHSR intends to continue and expand its efforts to arrange conferences and to initiate extensive discussions with public and private authorities in order to identify and establish the importance of particular issues.

The decision on what to study should be based not only on the importance of the issue but also on the likelihood that research will provide information that will contribute substantively to the policy-making process at a micro or macro level. Accordingly, the NCHSR also consults with professionals who have been working on and studying the issues identified. Each major issue then selected by the Director as a priority concern is submitted for review to an assembled group of experts from within and outside the Center. Their task is to determine what questions should be asked to elucidate the nature of the problem, the validity of current policy assumptions, and the likely impact of proposed programs or policies. The groups are asked to assist the staff in the development of specific research projects that will clearly be useful and feasible.

The decisions regarding what research to support must be made by the NCHSR. Here the interests of the various constituents and the technical information can be synthesized into a scientifically sound, reasonably balanced, and responsible research agenda. The NCHSR gives priority to those initiatives that appear most likely to generate policy-relevant results.

Health services research or scientific inquiry to produce knowledge about the structure, processes and effects of health services is supported throughout the Public Health Service (PHS) and Health Care Financing Administration (HCFA). However, in contrast to the broad and general research mandate of NCHSR, the PHS agencies and HCFA conduct program-oriented health services research in support of their primary missions.

There is considerable complementarity of interest between the general research agenda of NCHSR and the program-related research agendas of HCFA and the PHS agencies. Consequently, a number of procedures have been established to assure that the most effective research strategy for all organizations can evolve. These procedures are directly responsive to the coordinative role in health services research which NCHSR is mandated to implement under the PHS Act as amended by P.L. 95-623. Highlights of these ongoing coordinative activities include:

- Periodic meetings of a formal, senior-level PHS Health Services Research Coordinating Committee where new initiatives are discussed prior to implementation and program interests are shared.

- Routine exchange of the face sheets and abstracts of all grants.

- All NCHSR contract and grant research that is specifically program dependent is regularly discussed with the appropriate PHS agency or HCFA prior to an NCHSR commitment to pursue the study.

- PHS and HCFA staff have been invited to attend NCHSR scientific review committee activities, and the staff of NCHSR have routinely participated in the review process of other agencies.

- NCHSR and HCFA have produced a Joint Health Services Research Strategy and Budget during the past two fiscal years. Information is provided which highlights the extensive interaction between the two agencies for planning purposes, the complementarity between each organization's research efforts, and the specific priorities and estimated budget obligations for the areas of research supported.

These information and decision-sharing procedures, coupled with a significant difference in emphasis--for the PHS agencies and HCFA, the program support focus is predominant, while for NCHSR the general issues are more compelling--lead to a research agenda that reflects a high degree of complementarity and mutual productivity. NCHSR, HCFA, and the PHS agencies will continue to invest in improving their capacity to identify under-supported research areas which can be strengthened by cooperative and coordinated effort.

FY 1981 Budget for NCHSR
(In Thousands)

Extramural:		
	Research grants	$17,088
	Research training	500
	Contracts	2,835
	Other	---
	Subtotal	$20,423
Intramural		5,356
Dissemination activities		1,000
Other		7,755
	Total	$34,534

Mission of NCHSR

The National Center for Health Services Research undertakes and supports research, demonstrations, and evaluations on problems in the organization, delivery, and financing of health care services; serves as the focal point for coordination of health services research within the Public Health Service; and disseminates the findings of health services research to policy- and decision-makers in the public and private sectors.

As the only general-purpose independent health services research agency, NCHSR conducts and supports research, demonstrations, and evaluations concerning the delivery of health services. Specifically, NCHSR undertakes and supports projects respecting--

- The accessibility, acceptability, planning, organization, distribution, utilization, quality, and financing of health services systems;
- The supply and distribution, education and training, quality, utilization, organization, and costs of health manpower;
- The design, utilization, organization, and cost of facilities and equipment; and
- The uses of computer science in health services delivery and medical information systems.

NCHSR is responsible for expanding the health services research capacity in the United States. To this end, the agency--

- Undertakes and supports an active program to provide effective and timely dissemination of the findings of research by means of publications, press releases, conferences, and workshops;
- Supports the development and operation of general extramural research centers and special extramural research centers to study problems in health care management, health care technology, and health services policy analysis; and
- Undertakes and supports manpower training programs to provide for an expanded and continuing supply of individuals qualified to perform the research, demonstration, and evaluation activities related to the delivery of health services.

The NCHSR research effort is directed toward developing new options for the delivery of health services, testing the assumptions on which current health policies and practices are based, and developing improved methods for monitoring the performance of the health care system.

The NCHSR research program provides needed information to government, the health industry, and consumers of health services. NCHSR relies heavily on an ongoing relationship with policymakers and program administrators at the Federal, State, and local levels, with health care providers, and with

consumers. NCHSR shapes research priorities to meet the needs of these groups and informs them of research findings in a timely and effective manner.

Classification of Projects in the NCHSR

The NCHSR has identified the following 10 issue-based areas or categories of research:

Health promotion and disease prevention

Service delivery for the disadvantaged

Health care costs and expenditure

Health insurance and finance

Health manpower

Planning and regulation

Technology and computer science applications

Quality of care

Emergency medical services

Long-term care

An eleventh category, called special studies, has been set aside for research projects that examine methodological programs in the health services research area. Because the set is based on issues, the expenditures in any given area may fluctuate substantially from year to year. Further, the categories may also change in number. However, the issues are relatively broad and of fundamental concern in public policy.

National Center for Health Statistics

The FY 1981 budget for the National Center for Health Statistics totals $38.7 million. The activities of NCHS include statistical research and serve other research programs of PHS and other agencies.

Office of Health Research, Statistics, and Technology

A Selection of Recent Major Planning Reports of the OHRST

Copies of the documents listed below may be obtained by contacting (301) 443-1927.

Office of Health Research, Statistics, and Technology

Annual Report to Congress on the Administration of Sections 304 to 309 of the Public Health Service Act, December 1979

National Center for Health Care Technology

Report of the National Council on Health Care Technology, 1979

Report of the Subcommittee on Criteria of the National Council on Health Care Technology, 1980

Research Grants Program Description: Health Care Technology Assessment, 1980

National Center for Health Services Research

NCHSR Program Statement: Mission and Description of Research Programs, 1980

General Grant Solicitations: e.g., Multi-Institutional Arrangements, 1980, and Prevention and Promotion, 1980

Chapter 6

HEALTH SERVICES ADMINISTRATION

Agency head:

Dr. George I. Lythcott
Administrator
Health Services Administration
Parklawn Building, Room 1405
5600 Fishers Lane
Rockville, Maryland 20857
(301) 443-2460

Planning contact:

Mr. Ronald H. Carlson
Associate Administrator for
Planning, Evaluation and
Legislation
5600 Fishers Lane
Rockville, Maryland 20857
(301) 443-2460

Other contacts:

Dr. Edward D. Martin
Director
Bureau of Community Health Services
Parklawn Building, Room 705
5600 Fishers Lane
Rockville, Maryland 20857
(301) 443-2320

Dr. John Hutchings
Chief, Research and
Training Services Branch
Parklawn Building, Room 744
5600 Fishers Lane
Rockville, Maryland 20857
(301) 443-2340

Dr. Emery A. Johnson
Director
Indian Health Service
Parklawn Building, Room 5A55
5600 Fishers Lane
Rockville, Maryland 20857
(301) 443-1083

Dr. Ervin S. Rabeau
Director
Office of Research
and Development
Indian Health Service
P.O. Box 11340
Tucson, Arizona 85734
(602) 792-6600

Dr. James H. Erickson, Director
Bureau of Medical Services
Room 1120
6525 Belcrest Road
Hyattsville, Maryland 20782
(301) 436-6211

Dr. Richard K. Hsieh, Chief
Research Coordination
Branch, BMS
Room 1175
6525 Belcrest Road
Hyattsville, Maryland 20782
(301) 436-6214

Chapter 6

HEALTH SERVICES ADMINISTRATION

The Planning Process

The Health Services Administration is concerned with providing high-quality, effective, and efficient health care to both disadvantaged and special population groups. In view of the diverse needs and the scope of health problems of its statutory-based populations, the HSA offers a unique setting for health research opportunities. The responsibility for research efforts rests with HSA's three Bureaus: the Bureau of Medical Services (BMS), the Bureau of Community Health Services (BCHS), and the Indian Health Service (IHS). Although the planning process for the research activities within each Bureau differs, it is consonant with the agency's mission and mandated activities. Studies are designed to provide results that will inform policy decisions and contribute to improved quality and management of health services.

In BMS the development of a research program is overseen by the Research Coordination Branch, Division of Hospitals and Clinics (DHC). In cooperation with Branch staff, research information needs are primarily assessed by the Health Services Research Council, established within the DHC. The Council receives broad representation from the following members: the Director and Deputy Director, DHC; the Chiefs of the HSR Clinical Research Section and Research Coordination Branch, DHC; Directors of each HSR Center; two PHS Hospital Directors; one Associate Director for Hospital Administration; and one PHS Clinic Director. Additional Council members are the Chief of the Intramural Research Section, National Center for Health Services Research, and representatives from the health care industry, from health researchers in the academic community, and from Government organizations such as the Department of Defense, the Veterans Administration, and the agency's IHS.

The Research Council's responsibilities include recommending research priorities, monitoring the quality of research programs, and reviewing and making recommendations to the Director of the Research Council in the following areas: policy for the Bureau's HSR; approval of proposals to establish new health services research centers; approval of HSR activities or programs to be conducted at any of the HSR sections or centers; distribution of available resources; the establishment of research affiliations; and initiation of research projects and developing requests for proposals. As a final responsibility, the Council annually reviews the status, quality, and effectiveness of ongoing HSR programs and recommends continuation or changes where necessary.

In the BCHS, the Maternal and Child Health (MCH) research grants program relies on investigator-initiated research. Thus, plan development, per se, does not occur.

In the IHS, the Office of Research and Development (ORD) coordinates the research activities. Requests for services by the ORD are initiated by intertribal agencies, urban Indian groups, and individual Indian service units. In addition, the ORD has received requests and subsequently developed joint projects with other Government agencies such as the National Center for Health Services Research, the Office of International Health, the National Aeronautics and Space Administration, and the U.S. Army Medical Command.

In every instance in which technical assistance is provided specifically for the problem identified, the underlying problem that generated the request must be shared by many elements in the total IHS system or many Indian groups. In such instances, the following factors are ordinarily present: the potential benefits from a detailed research and development project appear to be large; the project appears to be feasible; the resources required to conduct the project are available; and the project would probably be given a high priority for research and development. In some instances, the relative rankings of previously established project priorities are altered to accommodate the new effort. In addition to projects that evolve out of externally generated requests, the staff of the ORD initiates the development of project proposals to fill the identified knowledge gaps in health services delivery.

Mission and Programs

The mission of the HSA is to administer programs concerned with the delivery of health services to a population that is basically composed of socioeconomically depressed individuals who lack adequate primary medical and social services. To accomplish its mission, the HSA strives to deliver health services that are accessible, adequate, appropriate, and acceptable. The HSA activities include building and maintaining primary health care capacity in underserved areas, improving the organization and efficiency of health care delivery and promoting effective and equitable public health and preventive services. The HSA accomplishes these efforts through three major organizations: the Bureau of Community Health Services (BCHS), the Indian Health Service (IHS), and the Bureau of Medical Services (BMS).

HSA research efforts are mission-oriented, problem-initiated, and primarily designed to contribute to meeting the critical need for improved quality, efficiency, and economy in the delivery of health services. Health services research in the HSA is based on scientific inquiry to produce knowledge about the structure, processes, and effects of health services. It embodies a wide range of financial, delivery, organizational, and systemic issues. The agency's research priority is the development, application, and conversion of this knowledge for the purpose of improving the health status of its target populations.

The Health Services Research Plan, recently completed, outlines major research priorities in each Bureau for 1981.

Bureau of Medical Services

In the area of health care costs and expenditures, there are two ongoing studies, "Clinical Algorithm Validation" and the "Upper Respiratory Illness Cost Containment Study."

A key project in the Emergency Medical Services area is the examination of poison control centers with a view to establishing the direction for such centers in terms of size, geographic coverage, and scope of preventive services.

The results of an analysis of a Geriatric Day Treatment Center are expected to relate to the Department's development of alternatives to institutionalization of the elderly.

There are three ongoing research projects within the area of technology and computer science applications:

- Evaluation of Ambulatory Care Data System (ACDS),
- Public Health Automated Medical Information System (PHAMIS), and
- Evaluation of the Patient Held Medical Record.

In the ACDS study, a patient management system is expected to be developed that will aid in improving patient care. With regard to the PHAMIS project, it will automate components of the inpatient clinical information. This should lead to improved quality of care, higher staff productivity, and cost containment. In the third study, the role of the patient in handling his own medical records is being tested and studied. It is hoped that the results will show improved continuity of care, fewer medical accidents, and improved health education opportunities.

Bureau of Community Health Services

Research activities are concerned exclusively with delivery of health care to mothers and children. The majority of the health services research currently funded by the MCH Research Grants Program fall in the Special Studies subdivision.

All the studies, for the most part, address relevant issues and questions of public policy related to the effectiveness of MCH program supported at the State level under Title V legislation. Some of the special studies seek also to evaluate innovative ways of delivering health care to mothers and children. For example, two of the studies examine in detail service needs and utilization of services by children with physical disabilities, chronic diseases, and psychosocial problems. Findings of these two studies will have policy implications for national health insurance, implementation of new education legislation (P.L. 94-142), and needed changes in crippled children's program services.

Indian Health Service

In the health service delivery area, two major projects are examining outpatient clinic operations. One involves the design of a model outpatient clinic. And an Operating Room Management Information System (ORMIS) was developed as a result of studies in operating room management. Work continues to expand the utility of this information system.

In the area of technology and computer science, applications work continues in the testing and evaluation of the Patient Care Information System (PCIS) developed by IHS. Planned for FY 1981 are further quality-assessment studies in the pilot areas in which this system is being tested.

In the health manpower area, projects are ongoing in two major areas: determination of the most efficient mix of skills to perform each of the functions within the health care system, and redefinition of health care functions to include a greater role for the technician and paraprofessional.

In the area of quality of care and emergency medical services, criteria were developed and a methodology implemented for examining the effectiveness of emergency facilities. As implemented, they will upgrade emergency room capability.

Budget

The agency's total budget for fiscal year 1981 is approximately $2.1 billion (includes Indian Health Service). Of that, $4 million is devoted to research activities, as specified in the following table:

Health Services Administration

FY 1981 Budget for Research
(In Thousands)

Health promotion and disease prevention	$	150
Service delivery for the disadvantaged		145
Health care costs and expenditures		50
Health insurance and finance		--
Health manpower		316
Planning and regulation		137
Technology and computer science application		1,433
Quality of care		135
Emergency medical services		600
Long-term care		32
Special studies		1,108
Research Total	$	4,106

FY 1981 Budget for the Agency
(In Thousands)

Extra- and intramural research	$	4,106
HHS Health Research Initiatives:		
Population		(3,000)
The Individual Consumer in Health		(150)
Other		2,111,663
Agency total		$2,115,769

Health Services Administration

Planning Reports

Health Services Administration Forward Plan, FY 1979-1983

Health Services Administration Plan, FY 1980-1981

Health Services Administration Plan, FY 1982-1984

Health Services Research Plan, FY 1979-1981

Chapter 7

HEALTH RESOURCES ADMINISTRATION

Agency head:

Dr. Karen Davis
Administrator
Health Resources Administration
Center Building, Room 10-37
3700 East-West Highway
Hyattsville, Maryland 20782
(301) 436-7200

Planning contact:

Mr. Lyman Van Nostrand
Director, Division of Planning
Office of Planning, Evaluation, and Legislation
Center Building, Room 10-22
Hyattsville, Maryland 20782
(301) 436-7266

Budget contact:

Mr. John Buckley
Director, Division of Financial Management
Office of Operations and Management
Center Building, Room 10-44
Hyattsville, Maryland 20782
(301) 436-7145

Chapter 7

HEALTH RESOURCES ADMINISTRATION

The identification of research needs in the Health Resources Administration depends to a great extent on the type of research supported and whether or not it is policy-related. Research defined as policy-related tends to consider the information needs of the Department to a greater extent than research designed to expand the scientific base in a given area.

As an example, nursing research grants are geared to expanding the scientific base underpinning nursing practice, education, and administration rather than to explicitly serve as a source of data for the purpose of government policy-making. Major sources of input for determining research needs are the nursing profession itself and the nursing research community.

Planning in this area is based on national needs perceived through interaction with the community of nurse scientists, and a recent specific mechanism was the convening of a conference that achieved a focused expression of directions that nursing research should take in the next 10 years. The program is also responsive to the National Academy of Sciences' Report on "Personnel Needs and Training for Biomedical and Behavioral Research," particularly in terms of the recommendation that research in doctoral programs in schools of nursing needs to be strengthened. One step in this direction was the inauguration of Nursing Research Emphasis Grants for doctoral programs in nursing, which aimed at stimulating the development of nursing research related to the health needs of the Nation and enhancing the research efforts and resources of the faculty members. Each applicant school was encouraged to focus its studies in one specific area of emphasis as a means of becoming a center of excellence in that field and as a way of producing increased knowledge about populations with major health needs, such as the elderly and high-risk children. Priority-setting has not been done in the past, but is being considered as a possible mechanism for promoting national priorities such as those emphasized in "Healthy People."

Research training in nursing is supported by the National Research Service Awards predoctoral and postdoctoral fellowship program and institutional grant program of the Division of Nursing. In the 1977 Report of the Committee on a Study of National Needs for Biomedical and Behavioral Research Personnel, the Committee noted that predoctoral research training continued to be the appropriate level to meet the urgent need for doctorally trained individuals capable of providing research and teaching leadership in nursing. Further, it was recommended that up to 15 percent of the total number of awards should be made at the postdoctoral level. Opportunity for postdoctoral training was considered important, since nurses who had completed their doctoral training

in prior years would need to update their research skills to keep up with recent advances in nursing research. In addition, the Committee recommended an expansion of institutional training awards to permit the development of nursing research.

Research in an area such as health planning and its effect on cost containment, on the other hand, is more highly influenced by Department information needs than those of the research community, because of the closer link to policy interests.

Research needs are frequently identified through the Department's major health initiatives and the planning, legislative, budgetary, and management processes. State and local government information needs are identified by maintaining liaison with organizations such as the Council of State Governments, the Association of State and Territorial Dental Directors, the National Governors Association, and the American Health Planning Association. Additionally, there is a continued examination on the part of agency officials to identify research areas where efforts for improvement or expansion of present capabilities would be fruitful.

FY 1981 Budget
(In Thousands)

Extramural research:	
Research grants	$ --*
Research training	--*
Contracts	2,500
Other	--
Research subtotal	2,500
Nonresearch activities	453,976
Agency total	$456,476

*The President's Budget for FY 1981 did not request any funds for nursing research grants or nursing research fellowships. In FY 1980, nursing research was at a level of $5 million and nursing fellowships were at a level of $1 million.

Mission and Programs

The mission of the Health Resources Administration (HRA) is to identify health care resource problems through a careful assessment of the health care system; to recommend changes to improve that system in terms of improving ac-

cess to health care, improving continuity of health care, assuring reasonable costs of health care, assuring equal access to health education, and enhancing the Federal, State, local, and private partnership to address these issues; and to stimulate priority changes through program action to improve both the health care system and individual health status.

Program activities are carried out through the Bureau of Health Professions, Bureau of Health Planning, Bureau of Health Facilities, Office of Graduate Medical Education, and the Office of Health Resources Opportunity.

HRA carries out a limited program of research based on the types of legislative authorities available to it. Within the Bureau of Health Professions (BHP), the Division of Nursing is provided with specific research authority under section 301(c) of the Public Health Service Act. Funding in total for research grants under this section is projected at $5 million in FY 1980. For FY 1981 the President's Budget did not request any funds for nursing research. Congressional action in this area is not yet known. A limited number of research projects are also carried out under contract authority by the Division of Dentistry, Division of Medicine, the Division of Associated Health Professions, and the Division of Health Professions Analysis.

Additional research and analytical activities are carried out by the Office of Graduate Medical Education (OGME), which was established in 1979 as the focal point for activities related to the graduate phase of physician education.

Bureau of Health Professions

The Bureau of Health Professions provides national leadership in coordination, supporting and evaluating the development and utilization of the Nation's health professions personnel. Its research activities have been defined primarily by legislation specifically authorizing research activity in the nursing area and, in part, by particular identified program needs. During FY 1981, research activities are expected to include a variety of grant-funded studies in the nursing area as well as selected contract activities in the other Divisions.

Nursing. Nursing research focuses on the role of nursing care in the prevention of illness, care of the sick, and the promotion and restoration of health. Although it relies upon and utilizes the substantive scientific information and methodology provided by the other biological and behavioral sciences, it dif fers from those other scientific areas in that the focus is on the relevance to nursing rather than other aspects of health care.

Nursing research activities involve a variety of studies initiated both by individual investigators and by groups of investigators who are collaborating in several studies focusing on a single theme. The majority of the studies investigate behavioral, biomedical, and clinical areas pertinent to the science and artistry of nursing practice; the education of nurses; the application of research findings to nursing practice; and the development of tools and methods for use in nursing practice and research.

Typical are studies concerned with the impact of innovative nursing interventions on increased well-being and effective social functioning of individuals and groups with chronic and debilitating disease; studies addressing methods of maximizing quality of nursing care and minimizing costs; studies of the role and effectiveness of nurse practitioners in giving primary care; and studies of the continuing competence of nurses in providing primary, secondary, and tertiary care.

Dentistry. Dentistry research efforts focus on developing and applying new knowledge, concepts and techniques in dental education, educational institution development, and dental services. The aim is to increase the efficiency and effectiveness of the dental educational process, equalize access to quality care at reasonable costs, and improve practice configurations for delivering care. The assessment of preventive techniques is being addressed by studying the feasibility of developing an index of oral health--a measure to detect differences in oral health that can be attributed to factors accessible to control and change through prevention or treatment. If the feasibility study is suc- cessful, development of the index will begin in FY 1982.

New dental research projects expected in FY 1981 will be directed toward comparing the price of dentistry received in traditional settings versus retail stores, determining the impact of dental advertising on the service prices as well as the impact of a new type of paradental provider on the treatment of edentulousness, and determining the feasibility of creating a measure to convert patient self-assessments of dental needs into quantifiable estimates of required services.

Medicine. A major thrust in the research field of health personnel development involves physician competence assurance. The intent of this activity is to develop one standard examination that can be used to admit physicians to graduate medical training, as opposed to U.S. citizen graduates taking one examination and foreign medical graduates another.

Health Professional Analysis. A major goal of the health professions analysis program is to develop an equilibrating model of medical care delivery to supplement and eventually replace the present utilization/trend-based forecasts of health personnel requirements from the model currently used. The development of a model of the interaction of supply and demand factors in the delivery of medical care is a lengthy, difficult task. Attention is presently being given to the conceptualization and in-house development of a full prototype model of the medical care sector. To further develop the equilibrating model, FY 1981 efforts will focus on (1) the effect of technological progress on the demand for hospital and medical care so that this component can be added to the model demand functions and (2) the development and testing of alternative indices of health service quality and efficacy.

Of further use in the econometric model of national health care expenditures is the development of a hospital sector submodel for forecasting health personnel requirements stemming from major changes in care delivery. This study will develop a model relating cost containment and hospital reimbursement policies to care supplies and demand. Such a submodel will become a val-

uable component of the overall model in estimating the impact of national health insurance and other major changes in care delivery on employment in the hospital industry.

There will be continued development of the physician shortage area forecasting model which is designed to project physician shortages in inner-city areas under selected policy assumptions. A new area of research will examine physician distribution data at a subnational level. This will be the initial effort in developing a physician distribution microeconometrics model to examine and identify factors contributing to physician distribution patterns at local levels. Both endogenous and exogenous factors will be considered.

Associated Health Professions. The objective of the research in the area of associated health professions is to clearly identify and verify the essential practice requirements and related competencies of the entry-level professional to serve as a basis for the development of innovative evaluation instruments, educational resource documents and continuing competency resource materials. The focus in FY 1981 will be on the verification and refinement of role delineation for the field of health education. In collaboration with practitioners, clinical providers and educators, the contractor will identify, refine and verify (through sampling actual practice) essential competencies for application to practice. The results will provide a base for the development of national standards, relevant educational/training programs, training programs, competency-oriented evaluation instruments, and mechanisms to ensure the competency--both initial and continuing--of health professionals.

Office of Graduate Medical Education

The Office of Graduate Medical Education (OGME) in the Office of the Administrator, HRA, was established April 4, 1979, as the focal point for activities related to the graduate phase of physician education. Some of the major activities of OGME are defined, at present, by the Charter of the Graduate Medical Education National Advisory Committee, signed May 1, 1978, and extending through September 30, 1980. The OGME serves as the primary staff resource of the Committee. OGME also pursues research interests and functions that transcend not only the present Charter life of GMENAC, but also GMENAC's more limited focus.

The process for identifying physician manpower shortages and surpluses by specialty and geographic areas is dependent upon the existence of clearly understood health service and health status goals, a sophisticated data base, and a methodology for conducting analyses in a scientifically defensible manner.

A number of the intramural and extramural efforts of OGME are the result of or in support of GMENAC's activities. Such efforts relate strongly to an analytic modeling framework developed by the Committee, and generally involve methods and data necessary to estimate current and future physician supply; estimate present and future requirements; bring supply closer to requirements by influencing the number and mix of GME positions; determine task delegability to and substitutability of nonphysicians; and convert full-time equivalent physicians into functional headcounts by adjusting for such factors as continuing medical education requirements, teaching, the research/administrative responsibilities, and practice-time spent outside of the designated specialty.

Chapter 8

HEALTH CARE FINANCING ADMINISTRATION

Agency head:

Mr. Howard Newman
Administrator
Health Care Financing Administration
Hubert H. Humphrey Building, Room 310G
200 Independence Avenue
Washington, D.C. 20201
(202) 245-6726

Research and planning contacts:

Dr. James Kaple
Acting Director
Office of Research, Demonstration and Statistics
HHS Building, Room 4228
330 Independence, S.W.
Washington, D.C. 20201
(202) 472-7431

Dr. Judith R. Lave
Director
Office of Research
HHS Building, Room 4242
330 Independence, S.W.
Washington, D.C. 20201
(202) 472-7437

Chapter 8

HEALTH CARE FINANCING ADMINISTRATION

The Planning Process

While HCFA participates in Departmental initiatives, such as the demonstration of new ways to organize long-term care services at the community level, its own programs are the primary focus of its research planning process. In fact, research to improve the administration and effectiveness of its $54 billion financing programs is specifically mandated in HCFA's authorizing legislation.

The development of research priorities is the result of a lengthy planning process within HCFA and between HCFA and the Department. Various Departmental task forces review the need for research activities in a number of areas related to HCFA programs -- hospital rate-setting, primary care, etc. Through HCFA's participation on these task forces and through Secretarial direction, the agency integrates Departmental priorities into its research plans.

Within HCFA, the development of research priorities is the result of a dynamic ongoing interchange among research, policy, and operating program components. The research staff is familiar with emerging new research opportunities that are suitable for further pursuit. Policy and legislative staff are familiar with emerging policy issues that require research approaches. Operating programs are familiar with programmatic needs for research activities. This ongoing process culminates in an annual HCFA research planning conference at which HCFA's research priorities are set for the coming year. The product of this process and conference is HCFA's research spending plan.

Beginning in FY 1980 HCFA added a new facet to the research planning process. HCFA research staff have begun to develop state-of-the-art papers as a vehicle to stimulate discussion of the agency's research priorities. These papers will be circulated within HCFA and the Department and will provide a common ground for research planning.

Mission and Programs

HCFA annually funds over one quarter of the Nation's health expenditures to provide health care to approximately 45 million aged, poor, and disabled individuals. It finances these health services through the Medicare and Medicaid programs. The Medicare program provides health insurance for persons 65 years of age or over, and for disabled beneficiaries and persons

with chronic renal disease. The Medicaid program provides grants to States to finance health care services for pubic assistance recipients and other low-income individuals and families. In addition to financing these health services, HCFA has the responsibility to ensure that its beneficiaries receive quality health care that meets professional standards. Thus, HCFA contracts with local groups of physicians called Professional Standards Review Organizations (PSROs) to review the quality of services delivered to Federal beneficiaries and with State agencies to certify the conditions upon which health facilities participate in its programs.

As part of its effort to ensure that quality health care is delivered at the lowest possible costs, HCFA's Office of Research, Demonstrations, and Statistics studies and develops new ways to make HCFA's multi-billion dollar programs more efficient and effective. HCFA annually conducts over 300 intramural and extramural research, demonstration, and evaluation projects. These projects seek alternate ways to finance, organize, and deliver health services, as well as assess the impact of Federal programs on health care costs, providers, and beneficiaries. In FY 1981, HCFA will conduct research and demonstrations in the following program areas:

Hospital Costs. This program area is designed to develop economic knowledge about hospital reimbursement behavior in order to respond to policy questions regarding changes in reimbursement systems and how these systems can improve the Federal and State third-party payment programs. It will support the efforts to develop and compare alternate reimbursement systems in anticipation of broader Federal authority for controlling inflation in hospital costs. Also included in this area are studies to demonstrate and evaluate the hospital cost containment potentials of alternative prospective payment and rate-setting systems. In FY 1981 new research will focus on developing and testing case-mix-adjusted reimbursement measures for total hospital costs.

Physician Reimbursement. This program area focuses on physician costs and physician reimbursement. As the central decision-makers in the health care delivery system, physicians are directly and indirectly responsible for a large part of health care spending. This area includes descriptive and behavioral analyses of physician productivity. It also includes development and analyses of the impact of various reimbursement controls such as relative value scale systems and fee schedules. Projections, simulations, and actuarial analyses of historic data, physician supply, insurance prices, utilization, expenditures and incomes, and alternative reimbursement methods will also be performed. In FY 1981 new demonstration projects will be initiated to test alternative reimbursement methods for physician services such as risk sharing and to increase physician participation in the Medicare and Medicaid programs.

Long-Term Care. Long-term care is defined as care for the chronically ill and the physically or mentally disabled and includes a wide variety of health, social, and personal care services generally needed over an extended period. Long-term care services can be rendered in institutional settings as well as in ambulatory and home settings. This program area will focus on describing the characteristics of the populations in need of care, analyzing

and evaluating the economics of the long-term care service industry, factors affecting utilization of various types of long-term care services, and quality and utilization control mechanisms such as PSRO longterm care reviews. In addition, demonstrations will be conducted and evaluated on the costs and benefits of institutional care and alternative financing and reimbursement mechanisms. The hospice demonstration will be continued, as will demonstrations to test comprehensive ways to coordinate and deliver long-term care services at the community level. In FY 1981, development will begin for a new long-term care household survey, as a companion to the institutional population survey.

Health Systems Organization. This program area focuses on alternative approaches for delivering health care and seeks organizational and payment methods that reduce costs without adversely affecting quality. Research and demonstration projects will be conducted that address the following: approaches to alternate delivery systems for providing comprehensive care to HCFA beneficiaries; alternative incentives for HCFA beneficiaries to enroll in comprehensive health care organizations; the cost and quality impact of broadening Medicare and Medicaid coverage for new services and providers, including urban clinics and community mental health centers; development of child health assessment programs; and evaluation of the effectiveness of cost-saving strategies in the end-stage renal disease program. In FY 1981 new projects will be initiated to evaluate reimbursement issues in urban clinics and to study alternative physician reimbursement methods for the ESRD program and nonentitled renal patients.

Quality and Effectiveness. This program area is concerned with the issues of developing standards of care for Federal beneficiaries. Methods will be developed by which quality can be assessed. In addition, the application of these methods to different types of providers and health care settings, such as long-term care and end-stage renal disease, will be explored. Studies concerning variations in medical practice and the capacity to influence or modify such practice will be conducted. PSROs will be monitored, and the effects of focused review will be studied. Alternative utilization review systems as well as innovative approaches to survey and certification of health facilities will also be studied. In FY 1980 new projects will emphasize quality of care measures for long-term care.

Integrated Data System. This program area encompasses the development, testing, evaluation, and implementation of uniform billing, discharge, cost, and utilization data reporting systems, as specified in section 19 of P.L. 95-142, and their integration into a national health information network to serve the administrative and research needs of HCFA's operating programs. This area includes the implementation of a hospital cost-reporting system for Medicare and Medicaid; development of uniform cost-reporting systems for home health agencies, skilled nursing facilities, and health maintenance organizations; and testing of uniform billing and discharge data systems. New projects in FY 1981 will focus on developing uniform cost-reporting systems for other than hospital providers, such as long-term care facilities, and on identifying and adapting data outputs from the hospital reporting system to meet the needs of other HHS and State and local users.

Program Evaluation. This program area is designed to determine the effect of HCFA programs on their target populations and to analyze program management to determine its effect on the attainment of HCFA's programmatic goals. Three activities are encompassed in this program area: first, to plan and coordinate all HCFA program evaluation activities; second, to conduct selected program evaluation projects; and third, to be the principal point of contact with organizations outside of HHS on program evaluation matters. The PSRO program is currently under evaluation with a major report completed in 1979. A similar analysis will be completed in 1980. Evaluation work on the Maximum Allowable Cost for Drugs (MAC) program is also being completed. An evaluation design for the End-Stage Renal Disease program is being developed. In FY 1981 new evaluation activities will be directed at the EPSDT program, the Rural Health Clinics program, and Medicaid "reasonable cost-related" reimbursement of nursing homes.

Beneficiary Impact and Related Activities. This program area is designed to provide information on health care expenditures and utilization patterns of HCFA beneficiaries in order that HCFA programs may be more efficiently operated. The primary activities are to report and analyze the patterns and trends in health services utilization to determine if services are provided in as efficient and economical manner as possible; to assess the use and cost of program benefits as well as the use of uncovered services; and to determine the effectiveness of HCFA programs in removing barriers that prevent beneficiary access to health care services. In FY 1981, work will continue on the National Medical Care Utilization and Expenditure Survey, with completion of the field survey, initiation of an administrative records survey, and preparation of data for analysis.

Industrial Organization and Reimbursement. This program area will assess the effects of HCFA reimbursement policies on various industries in the health care sector, including clinical laboratories, long-term care, durable medical equipment, hospital supplies, and drugs. The purpose of these studies will be to understand how HCFA reimbursement policies affect the market structure and market performance of each industry. The relationship of industry suppliers to other providers in the health care sector, particularly with respect to pricing and utilization decisions, will be studied. In FY 1980-1981 projects will focus on examining the Medigap problem and demonstrating prudent buyer approaches for laboratory services.

Health Care Financing Administration

FY 1981 Budget
(In Thousands)

	FY 1980	FY 1981	Change
Medicare benefits (outlays)	$32,895,570	$38,286,480	16%
Medicaid vendor payments	13,063,056	14,770,015	
Administration/training	728,471	803,897	
Total (outlays)	13,791,527	15,573,912	13%
Budget authority*	14,240,094	16,234,052	14%
PSROs	155,220	192,668	24%
Outlays	55,718	59,250	
State certification	71,645	70,400	-2%
Outlays	70,263	68,912	
Research, demonstration, evaluation projects	46,782	52,357	12%
Outlays	37,426	46,385	
Medicare contractors	672,380	704,384	5%
Outlays	638,761	669,165	
ESRD**	(5,890)	(7,484)	27%
Outlays	(5,890)	(7,484)	
Beneficiary awareness***	(2,200)	(3,900)	
outlays	(2,200)	(3,900)	
HCFA administration	178,730	199,876	12%
Outlays	174,366	189,883	
Non-HCFA administration	317,543	321,207	1%
Outlays	328,449	319,210	
Subtotal, Outlays	$47,992,080	$55,213,197	15%
1980/81 Initiatives requiring Legislation	-3,243	-1,131,260	
1982 Initiatives requiring Legislation	--	--	
Total outlays	$47,988,837	$54,081,937	13%
Nonadd			
Payments to trust funds	$ 7,968,156	$ 9,589,120	20%

*Includes amount for Medicaid State Certification.
**Prior to FY 1982, ESRD activity was included in Medicare benefits.
***Prior to 1982, Beneficiary Awareness was treated as an administrative cost.

Health Care Financing Administration

FY 1981 Budget for
Office of Research, Demonstrations, and Statistics
(In Millions)

Hospital costs	$ 8.2
Physician reimbursement	5.4
Long-term care	11.6
Health systems organization	4.8
Quality and effectiveness	3.0
Integrated data systems	8.8
Program evaluation	3.8
Beneficiary impact and related activities	6.3
Industrial organization and reimbursement	.5
HHS Health Research Initiatives:	
Population	(.5)
The Individual Consumer in Health	(2.0)
ORDS total	$52.4

Part Two

HHS HEALTH RESEARCH INITIATIVES

Part Two

CONTENTS

INTRODUCTION

The Health Research Initiatives Defined

The initiatives described in this section are experiments in cooperative research planning and implementation by HHS health agencies. They are proposed as a new but supplementary element in Departmental planning and budgeting for health research.

Primarily, the initiatives focus upon selected problem areas where important mission needs of several HHS agencies coincide with significant scientific opportunity. For these areas, they represent efforts to strengthen research through cooperative planning and information exchange on a continuing basis. In this collaboration, each participating agency retains responsibility for the quality of science and program relevance of the activities it supports.

So defined, the initiatives represent a limited but new, feasible, and useful product of research planning from a Departmental perspective, with the specific advantage of easy coupling to the budget process. Clearly, the initiatives are a part of, and not a substitute for, the mission-wide research planning that each health agency must do for itself. Even less are the initiatives proposed as a substitute for the comprehensive assessments and related planning across all fields of health research which have been recommended to the Department from several quarters.

Each initiative stems from one or more of the health research principles approved by the Department in August 1979 to guide its health research investments. Concurred in by the Secretary, the initiatives will constitute an important component in evolving HHS strategy for health research support. Their program goals embody key support principles. Individually and together they highlight opportunities for cooperative attacks on major problems for which sustained intellectual and financial commitments are needed.

The initiatives not only reflect considerable variation in scale at their proposed start, but may be assumed to show equally wide variation in their potential for useful program growth in the future. Thus, it is important to note that approved initiatives cannot expect automatic priority in Department budget decisions. The status and needs of such initiatives will indeed be highlighted in budget processes, but for added resources they will have to compete with other research activities and with one another.

Concept Development

The present concept for HHS research initiatives--which remains essentially unchanged from that in the December 1979 document of the Steering Committee--evolved gradually during the spring and early summer of 1979. It is a product of discussions among HEW (HHS) Steering Committee members and their staffs, to which were drawn at various times the former Secretary, members of his staff, the Advisory Committee to the NIH Director, and the Institute of Medicine. As the Health Research Principles document was worked into final form in April and May, the Steering Committee turned seriously to options for applying the principles in actual budget planning for the fall.

As a first step, it was suggested that each agency identify short- and long-term research goals that are important to its needs and that tie in clearly to one or more of the approved principles for health research support. Later stipulations were that agencies identify possible research initiatives that would integrate similar activities of several HEW agencies and, moreover, lend themselves to longer-term planning. Finally, the Committee agreed that each initiative must have a mechanism for interagency research planning and coordination.

Nomination and Selection

By mid-May of 1979 the formal request went out to Committee members to nominate possible initiatives from their agencies' perspectives. The initiative concept was further clarified by a Director's Advisory Committee meeting at NIH in late June. There, agency representatives described cooperative research efforts presently under way in toxicology testing, influenza research, and population research. By mid-July, HEW health agencies had nominated more than 50 possible research initiatives, though some of these were later withdrawn. During the Spring of 1980, all agencies were again given the opportunity to nominate initiatives for consideration by the Steering Committee. The four new initiatives in this volume were developed at that time.

To sum up, the following criteria guided the Steering Committee in selecting each of the 15 initiatives recommended to the Secretary:

- It must be research--moreover, research directed toward a problem area where both need and scientific opportunity are clear;
- It requires participation by more than one HEW agency;
- It lends itself to a mechanism for research coordination;
- It should, if possible, project budget needs for 3 to 5 years; and
- It must relate to one or more of the approved HEW principles for health research support, and its description must identify this relationship.

The Proposed Initiatives

Eleven of the proposed HHS initiatives described hereafter are hardy survivors of the extended planning process that began a year and a half ago. These have been redrafted to take into account appropriate public and IOM comments and to further specify the nature of the health problem addressed and the scientific opportunities seen. Four other proposed initiatives were added for the July 1980 draft of this planning document. While all of the initiatives including those added appear to meet the required criteria, they vary in ways warranting some comment.

For example, the first 8 of the 11 initiatives that appeared in the December 1979 planning document of the Steering Committee were described as representing a more advanced stage of planning than the following 3. To some extent, this situation still prevails. While significant variations exist among initiative in the first group, all reflect discussion and agreement among agency sponsors and cosponsors on key points. The points of agreement included the anticipated scope of research collaboration, some consideration of goals, and at least tentative identification of current and planned resources. Most of these initiatives are based, in part at least, on preexisting cooperative arrangements--some quite formal and structured, as in the case of the National Toxicology Program, and others, like Alzheimer's Disease and the Dementias of Aging, with much less formal arrangements. In all cases they are felt to represent crystallized proposals that can be implemented soon after approval.

On the other hand, the subsequent three initiatives, as well as the four more recent ones, reflect tentativeness on a number of important planning features. While they address topics of current importance and satisfy other selection criteria for proposed initiatives, they lack detail on some or all of the following points: the scope of research concerns to be addressed, the nature and extent of involvement by proposed participating agencies, how the proposed coordinating mechanism will work, and agency estimates of resources to be deployed in the effort. (Two of the new initiatives, Prevention of Birth Defects and Research on Prevention and Control of Hypertension are designated as "Initiatives in planning status.")

For all of the initiatives, continuing agency commitment and progress toward implementation of planning processes will need to be monitored on a continuing basis by the Steering Committee or a successor coordinating group.

Required Resources

The resources outlined for each initiative represent a number of different approaches, though all figures have been prepared by agency budget staff. The FY 1981 figures have been coordinated carefully with the FY 1981 budget.

Because research project grants are a vital means of support for most research programs of NIH and some research programs of other agencies, there is considerable overlap between the resources shown for the stabilization

initiative and for several of the others. A similar but more limited instance of resource overlap occurs between the initiatives for the National Toxicology Program and the Prevention of Reproductive Effects Due to Workplace Hazards.

For some initiatives, agency resource commitments cannot be determined until interagency agreements have been worked out. This applies to Health Care Technology Assessment and to the participation of the National Center for Health Statistics in several of the initiatives.

The new initiative for Research Training reflects the latest training recommendations made by the National Research Council of the National Academy of Sciences, as mandated by the Congress. These represent a careful computation of future training needs in broad professional categories of the health sciences, rather than by agency.

It must also be noted that some of the new and expanded activities proposed through the initiatives will not be possible with the present manpower resources of the agencies. For those initiatives, consideration of manpower needs will be very important.

Chapter 9

STABILIZING THE SCIENCE BASE: RESEARCH PROJECT GRANTS

Sponsoring agency:

National Institutes of Health

Cosponsors:

Alcohol, Drug Abuse, and Mental Health Administration

Health Resources Administration
Division of Nursing

Center for Disease Control
National Institute for Occupational Safety and Health

Food and Drug Administration

National Center for Health Services Research

Initiative coordinator:

Dr. William Raub
Associate Director for
Extramural Research and Training
National Institutes of Health
Building 1, Room 107
Bethesda, Maryland 20205
(301) 496-1096

Chapter 9

STABILIZING THE SCIENCE BASE: RESEARCH PROJECT GRANTS

Purpose and Rationale

Efforts to combat human disease and disability are inevitably constrained by the extent and quality of the knowledge base from which they arise. Accordingly, the 1979 report of the HHS Steering Committee for the Development of a Health Research Strategy identified stabilization of the science base as a major planning need. The science base was defined as being made up of those activities oriented toward fuller scientific knowledge or understanding--as distinct from those oriented toward research on intervention in the health system (applications), transfer of research into end uses, and training of future generations of health investigators. Contributing to the science base are grant-supported research projects, grant-supported research centers and resources, research contract projects and intramural research (appendix A). As a first step, the 1979 report included an initiative to stabilize the funding opportunity for investigator-initiated research project grants.

Nature and Magnitude of the Problem

The best biomedical and behavioral research is conducted by professionals who must dedicate their careers to this purpose and undergo extensive training to compete successfully. If it is accepted that excellence is sustained by cyclical competition for continued support, then an equally important requirement is a predictable market for the ideas and skills subjected to that competition. Otherwise, research will cease to compete for the career attentions of the most gifted.

Today the predictability of research support appears to many participants to be so uncertain as to require some sign of commitment that extend beyond the single-year appropriations. Agreement of some reasonable targets ideally by both the Executive Branch and the Congress, would be highly desirable, even though all concerned recognize that such expressions of intent cannot be taken as binding commitments.

Relationship to Health Research Principles

This initiative is a partial implementation of the first Health Research Principle. It represents a major effort to translate into program terms the principle that "HHS must encourage and maintain strong, steady support of the search for fundamental knowledge necessary to meet the full range of health needs and expectations." Because the initiative addresses the needs of the

health research enterprise generally, rather than a specific health research problem, it differs somewhat from the other initiatives. However, it relates to them by providing the base from which the initiatives of a more catagorical nature may proceed.

Implementation of the 1979 Initiative

The 1979 initiative was affirmed and made operational in the FY 1981 President's budget for NIH, but not for the other two original participants--ADAMHA and HRA. The response on the part of the Executive Branch, the health research community and the Congress has been generally positive. This initiative seems to deserve further development in association with the FY 1982 budget process.

However, the initial implementation brought with it several problems that must be addressed as part of future steps. Given the constraints on total budget levels, this approach placed strict limits on the amount available through NIH for other activities, notably research training, R&D contracts, centers, and intramural research.

Concerns about the possibilities of strict limits on these and other research activities are shared by HHS program managers and by non-Federal advisors. For example, in its analysis of the HHS health research planning document, the Institute of Medicine expressed "grave reservations" about the level of activity in the area of research project grants, noting that "the focus on the need for 'predictable support' has been at the expense of the need that support be 'sustained and enhanced'". The IOM urges that the FY 1981 level for research project grants be viewed as a minimum and that long-range research plans be based on scientific opportunity, the burden of illness, and the potential to reduce that burden--recognizing, of course, that short-term budgetary constraints may dictate less than optimal choices. The IOM critique also calls for renewed attention to stabilizing the entire science base and argues that the analysis should include detailed discussion and planning of research training. The research community has similarly endorsed the concept of stability, but has indicated reluctance to sacrifice other elements of the science base in order to stabilize project grants. Of particular concern to the IOM and other observers--as well as program staff--has been the deleterious impact on research training, particularly the combined effects of limited budgets and stipend increases.

Both the IOM and the research managers have pointed out the importance of linking planning efforts more explicitly to program concerns. To this end, the research agencies have developed a variety of planning processes designed to identify the major areas of need and opportunity and to suggest strategies for focusing on these areas.

Proposed Next Steps

NIH, ADAMHA, and HRA continue to believe that maintenance of a stable base of competing research project grants represents the most important step toward stabilizing the science base. However, attention must be given to

other critical elements of the science base. If indeed the goal is to strengthen and nurture the discovery process underlying applications to human health, this process must be viewed as a whole, and it must be remembered that the various mechanisms for supporting science base activities all contribute in important ways to the entire enterprise. Thus, research centers and resources enrich the research environment and provide unique opportunities for interdisciplinary collaboration; research contracts permit the agencies to stimulate research in needed areas and to manage and coordinate complex undertakings such as clinical trials; and the intramural research programs provide a stimulating yet stable environment for high-quality laboratory and clinical investigations, as well as a resource for the national and international research communities.

Any effort to stabilize the science base must also take into account the important differences among the several organizational components of NIH and ADAMHA. These programs differ in size and degree of development and face different arrays of research needs and opportunities. In particular, ADAMHA believes that its constituent Institutes have not yet achieved adequate funding levels for research project grants; the need for growth above a stable base is especially apparent in the more recently established National Institute on Drug Abuse and National Institute on Alcohol Abuse and Alcoholism. Similarly, constituent Institutes of NIH differ markedly with regard to their size and stage of program development; moreover, each Institute is faced with a rapidly changing array of program needs and research opportunities, many of which could warrant expanding support for research project grants. A strategy that achieved aggregate stability for NIH and ADAMHA without regard to the special attributes and needs of their organizational components would be shortsighted.

New Cosponsoring Agencies

NIOSH

Stable funding for science base activites is key to the research responsibilities of the National Institute for Occupational Safety and Health of the Center for Disease Control (NIOSH/CDC). NIOSH research addresses the discovery or confirmation of information on the existence of or underlying mechanisms relating to occupational hazards and includes the development of innovative methods for minimizing or preventing them. NIOSH has been a relatively new source of research grant funding since receiving its research mandate in the Occupational Safety and Health Act of 1970. Stable and predictable funding to attract and maintain investigators in this field is essential to the building of a quality research program.

FDA

Although it has a relatively small research grant investment, the Food and Drug Administration believes that these projects are a valuable part of its science base activities. The greatest number of grants awarded by FDA have been in the area of radiological health. These grants have been for experimental and epidemiologic research to promote safe and efficacious use of radiation, with emphasis on the elimination or reduction of unnecessary

and unproductive human exposure. As required to carry out its regulatory mission, FDA also awards grants in the areas of poison control, drug hazards, veterinary drugs, medical devices, toxicological studies, and biologics.

NCHSR

The continuing stable support for the research community is no less important in health services research than in the biomedical and behavioral science fields. Indeed, the serious erosion of support for health services research has discouraged new investigators from entering the field and has forced more senior and sophisticated investigators to leave the field altogether or modify their skills to permit them to deal with problems in other areas of the social sciences. Viewed in light of the growing concern over the costs of medical care, criticisms of the efficiency and equity of the health care delivery system and various attempts to modify existing public policy, the decline of this research enterprise is a serious, if unrecognized, public issue. The public interest will be well served in both the short and long run by the adoption of a policy to stabilize, if not expand, the investment in the science base in the field of health services research.

Research Training

It should also be noted that research training, while recognized in the 1979 document as an important contributor to knowledge development, was treated as a derivative of the aforementioned research activities. Subsequent analysis and discussion have highlighted the interdependence of the scientific discovery process and the maintenance of a pool of well-trained investigators. Thus, a separate initiative designated "Research Training" is discussed in Chapter 21.

Resources

NIH and ADAMHA

Projections for NIH and ADAMHA appear in the attached tables.

HRA

The FY 1980 level of funding for nursing research activities is $5 million. The 1981 budget did not request any funds for nursing research, and the Congress has not yet acted.

NIOSH

With a research budget of $6.4 million in FY 1979, NIOSH awarded 76 new and renewal grants with an average award of $70,000. In 1980 the average award increased to $93,000, and 73 awards were made from a budget of $7.0 million. The President's budget for 1981 reduces the amount available

for research grants to $5.8 million. With grant awards projected at an average of $135,000, it is anticipated that only 50 awards will be made.

FDA

Within a total research budget of $66.2 million in FY 1981, FDA plans to award 7 new and renewal grants for an investment in its research grant program of $1.9 million.

Table 1. NIH RESEARCH PROJECT GRANTS
(Dollars in Millions)

Alternative	FY 1981
I. Significant (8%) growth	
Competing awards	4,884
Total awards	16,360
Current dollars	$ 1,714
Inflated dollars	---
II. Modest (5%) growth	
Competing awards	4,884
Total awards	16,360
Current dollars	$ 1,714
Inflated dollars	---
III. Maintenance of the 1981 level	
Competing awards	4,884
Total awards	16,360
Current dollars	$ 1,714
Inflated dollars	---

Table 2. ADAMHA RESEARCH PROJECT GRANTS
(Dollars in Millions)

Alternative	FY 1981
I. Significant (8%) growth	
Competing awards	593
Total awards	1,459
Current dollars	$ 139.5
II. Modest (5%) growth	
Competing awards	593
Total awards	1,459
Current dollars	$ 139.5
Inflated dollars	---
III. Maintenance of the 1981 level	
Competing awards	593
Total awards	1,459
Current dollars	$ 139.5
Inflated dollars	---

Addendum

ELEMENTS OF THE SCIENCE BASE

Research Project Grants. Representing the largest component of the science base, these grant-supported projects correspond roughly--though not precisely--to the investigator-initiated element generally viewed as essential to a vigorous, productive research enterprise. They include traditional research projects (R01), new investigator awards (R23), and program project grants (P01), ranging from fundamental to clinical investigations.

Research Centers and Resources. While both of these terms encompass a broad range of activities, they refer in the context of "science base" to programs designed to support and enrich the research environment at the performing institutions. Included are center core grants, comprehensive center grants, the Biomedical Research Support Program, and the Minority Biomedical Support Program.

Research Contracts. While most contracts of the health agencies represent applications for research or station support, a sizable fraction fund investigations spanning the full range of the science base. Research contracts are used to meet specific program needs, with the research performed either by profit-makers or nonprofit organizations. Agency involvement in development varies according to the project, but in general, research contracts are designed to fill knowledge gaps or pursue opportunities that, in the best judgment of agency staff and their external advisors, might not otherwise be pursued. Thus, they represent a major opportunity for the funding agencies to influence the direction of research.

Intramural Research. Research conducted by the health agencies encompasses most of the activities mentioned above. The research conducted at NIH is primarily investigator-initiated, where the existence of a stable environment has enabled intramural scientists to undertake innovative, long-range projects. The physical resources of the NIH campus--including its research hospital--have made it a magnet for Federal and private-sector investigators and for the international research community. NIH and ADAMHA intramural research ranges from basic biological sciences to clinical investigation, reflecting the breadth of the agencies' missions. Other agency research is similarly related to the agencies' mission--primarily knowledge-development aimed at providing the basis for improved health care or regulatory actions.

Career Development. A structured environment is necessary to permit the differentiation of the prepared fellow into an independent investigator. Availability of support for junior investigators during this critical maturation period is particularly important. These are the young people who have the imagination and skills to adapt the newest developments in science to

current problems. Their impact on the system cannot be overstated; from this group will come the true pioneers of science. While they are not yet established as totally independent investigators, they are not trainees. They comprise an essential and identifiable cadre of productive researchers who are an integral part of the research manpower continuum and must be included within the science base.

Chapter 10

NATIONAL TOXICOLOGY PROGRAM

Sponsoring agencies:

National Institutes of Health
- National Institute of Environmental Health Sciences
- National Cancer Institute

Food and Drug Administration
- National Center for Toxicological Research

Center for Disease Control
- National Institute for Occupational Safety and Health

Initiative coordinator:

Dr. David P. Rall
Director
National Institute of
Environmental Health Sciences
P.O. Box 12233
Research Triangle Park
North Carolina 27709
(919) 541-3201

Chapter 10

THE NATIONAL TOXICOLOGY PROGRAM

Purpose and Rationale

Nature of the Health Problem

The central reason for the development of the National Toxicology Program (NTP) is to protect the health of the American public from damage by exposure, often inadvertent, to environmental chemicals. Many human diseases can now be traced to chemical exposure--lung cancer to asbestos, arsenic, bis-(chloromethyl)ether, etc.; liver sarcomas to vinyl chloride; male sterility to Kepone and dibromochloropropane; and neurologic disease to Kepone, methyl mercury, lead, and methylbutyl ketone.

The Department of Health and Human Services is responsible for the Nation's health, and the prevention of human exposure to toxic chemicals is a keystone in its preventive health efforts.

Current estimates suggest that there are up to approximately 50,000 chemicals in commerce today in the United States. Approximately 5,000 of these are produced in quantities greater than 10 million pounds per year, suggesting the possibility of widespread and intense exposure. There are 5,500 food additives and 4,000 medicinal drugs. There is known human exposure to at least 1,200 additional compounds found in household products. The universe of chemicals to which we are exposed is therefore so large that it might appear to make the task of preventing human exposure to toxic chemicals impossible.

But the key word is toxic. While all chemicals can be shown to be toxic--that is, ultimately harmful at some dose or schedule--most are so relatively nontoxic that few controls, if any, are necessary to protect human health. For many other chemicals, moderate controls or restrictions--still allowing some exposure--will be adequate. Thus it is necessary for health protection and disease prevention to strictly control only a very small fraction of the chemicals in our environment.

Goals of the Initiative

The goal of the NTP is to strengthen HHS's activities in the testing of chemicals of public health concern, as well as in the development and validation of new and better-integrated test methods.

Specific goals for the program are--

- To broaden toxicological characterization of the chemicals tested;
- To increase the rate of chemical testing, within the limits of available resources; and
- To develop and begin to validate a series of protocols more appropriate for regulatory needs.

The program was established as a Department-wide effort to provide needed information to regulatory and research agencies and to strengthen the science base. It comprises the relevant activities of the Food and Drug Administration (FDA), the Center for Disease Control/National Institute for Occupational Safety and Health (CDC/NIOSH), the National Cancer Institute (NCI), and the National Institute of Environmental Health Sciences (NIEHS).

In addition to the sponsoring agencies listed above, participants in the program are the Occupational Safety and Health Administration, Department of Labor; the Consumer Product Safety Commission; the Environmental Protection Agency; the Office of the Director, National Institutes of Health; and the Office of the Assistant Secretary for Health.

Relation to Health Research Principles

This initiative relates primarily to the third Health Research Principle by providing for research that forms the basis of regulatory decisions affecting public health.

Implementing Arrangements

One of the central functions of the NTP is to serve as a focus for coordination of toxicology test development and testing among the relevant health research and health regulatory agencies. The principal instrument of this coordination is an annual plan that arrays the resources available to the NTP and the compounds it has on test and proposes to put on test in the forthcoming year. In order to ensure the effective interchange of research approaches and information, it is important that the NTP, with its orientation toward determining the toxic properties of chemicals, coordinate closely with those HHS research programs that are oriented toward specific diseases. In this way the NTP concern with how chemicals impact on specific organ systems can be linked to the concern with diseases of those systems.

The NTP has attracted widespread attention both inside and outside of government, and a number of organizations in this country and abroad have expressed an interest in participating in its activities. In addition, the NTP is linking its activities in the areas of toxicology data evaluation with international programs, such as the World Health Organization.

Because of the large scope of the task assigned to the NTP and the limited resources available to it, the program must be effective in its approach

to priority-setting. There are three mechanisms for aiding it:

- The Board of Scientific Counselors is responsible for reviewing the program for scientific adequacy and identifying program gaps.
- The Chemical Nomination Group, representing the Executive Committee, is responsible for nominating compounds for testing.
- The Executive Committee, composed of the heads of both the contributing and participating organizations, serves as the major advisory group. This Committee is responsible for advising the Program Director (who is also the Director of the National Institute of Environmental Health Sciences) on research and testing needs, and for setting priorities on the specific chemicals to be tested.

Relationship to Federal Research in Toxicology

For 1979, approximately $41 million in HHS funding was dedicated to the National Toxicology Program by NCI, NIEHS, FDA, and CDC/NIOSH. While this amount is the aggregate of most of the HHS environmental toxicology testing programs, it is by no means all of the Department's commitment to toxicology research, method development, and testing. The Annual Plans for the NTP include surveys of current HHS research related to toxicology.

Based upon various other analyses, there are considerable amounts in other departments and agencies committed to research in toxicology. While not all or even a majority of these amounts are specifically relevant to NTP, it is clear that toxicology is a major area of Federal research activity. Thus the NTP must develop closer and more effective coordination with other toxicology activities.

NTP Strategy

Essentially all the research and testing activities of the NTP relate to the goal of disease prevention, as expressed in the third Health Research Principle. They cover a wide range of health effects, but are all directed toward strengthening the HHS activities in the testing of chemicals of public health concern and in the development and validation of new and better-integrated test methods.

General Toxicology Strategy. Most of the chemicals tested by NTP are chosen because too little is known about their toxicologic effects. NTP's strategy for testing, which is a tier approach, begins with general toxicology testing to ensure that, insofar as possible, all major toxic effects that are life-threatening have been identified for each chemical to be studied in chronic tests. The goals are to broaden the toxicologic characterization of the chemicals and to uncover clues to other effects the chemicals may produce, such as damage to critical organs like the lungs, liver, and nervous system.

Such toxicology data are essential to the proper design of more extenive studies. Once NTP has learned those parameters that may be altered

through exposure to the tested chemicals, then additional toxicology capabilities (under the direction of scientists who are specialists in specific organ effects) can be used in a sequential fashion to confirm and define the toxicities identified by the screening process.

In its tier approach to toxicology testing, NTP first undertakes acute, repeated-dose, and subchronic studies of 90 to 120 days to learn the general target organ effects at different dose levels. The next level of testing requires a core of pharmacologic tests, including biological half-life, steady-state concentration, and time-to-steady-state of the chemicals or their major metabolites in plasma. Next, suspect chemicals are referred to specific organ-system groups for more detailed study of the functional, biochemical, and structural effects of the test compounds. They may also be referred to the pharmacokinetic and metabolism groups for wider analysis.

In total, this tier approach will yield a comprehensive characterization of the specific nature and duration of the toxic effects and the range of chemical doses over which the effects are observed.

Carcinogen Strategy. A major activity of the NTP, in terms of a financial and personnel commitment, is the performance of lifetime bioassays for carcinogenicity.

In funding allowed by the 1980 and 1981 budgets, the NTP plans to increase the levels of such testing from 79 new bioassays in fiscal year 1979 to a total of 80 additional tests in the two year fiscal period, 1980 to 1981.

Selection of chemicals for lifetime bioassays will be enhanced through the pretesting of chemicals in several short-term assays currently being validated. These tests include *in vitro* mutagenesis, *in vitro* cell transformation and *in vivo* tests such as the mouse lung adenoma assay. The results of these tests generally should identify those chemicals with presumptive carcinogenic potential that are the best candidates for the classic lifetime bioassays.

The results of lifetime bioassays will be more meaningful if proper doses are used, doses that are adequate but do not cause premature death. This will be accomplished by selecting doses based on a knowledge of the chemical distribution and metabolism, and establishing the number of doses and quantities of animals to be tested at each dose. The latter will maximize the statistical significance of the assay and the range over which carcinogenic potential is observed.

Protocol Development and Test Validation Strategy. The NTP is reviewing existing as well as newer test methodologies to determine which are adequately sensitive and reliable. The best will be selected and validated to ensure that they are effective.

Moreover, as basic research findings suggest new areas of toxicology testing, the NTP will develop and validate appropriate methods. Examples of existing methodology that are being examined for modification are those to detect liver or kidney function and neurobehavioral damage. New areas for methods development and validation include neurobehavioral toxicology,

immunotoxicology, and short-term tests for presumptive carcinogenic potential.

Validation of test methods is a two-stage process that involves determining, first, whether the procedure yields test results that are reproducible within and between laboratories and, second, whether it predicts toxic potential in man. The latter determination requires that the NTP pay close attention to the results of human epidemiologic studies that may correlate with test results.

Program Activities

The NTP has two major program activities: Toxicology research and testing, and coordinative management.

Toxicology Research and Testing. The NTP is uniquely capable of carrying out toxicology research and testing functions. Its components possess scientific expertise in toxicology, mutagenesis, and carcinogenesis; extensive laboratory facilities and animal testing skills; experience with carcinogen bioassays; and experience with human epidemiologic studies. Out of this reservoir of experience and knowledge, the NTP is developing an effective program to protect the Nation's health by--

- Developing a core methodology that defines general toxicologic response and screens for specific toxicities, such as effects on neurobehavior, fertility and reproduction, immunotoxicity, and skin, hepatic, and renal toxicity;

- Validating current mutational assays and developing new and comprehensive ones ranging from *in vitro* microbial and mammalian cell systems to *in vivo* mammalian systems; fostering the integration of genetic endpoints with those of other long- and short-term toxicology tests; and screening chemicals for mutagenicity;

- Determining the utility of current test methods for adequately predicting the likelihood that a chemical will cause developmental defects in humans, developing and validating a comprehensive battery of developmental and teratogenic tests, and screening selected chemicals to assess reproductive and developmental effects;

- Establishing the feasibility, relevance, and validity of behavioral testing procedures for measuring and predicting the effect of chemical insults on the nervous system; and expanding neurobehavioral test capabilities through the development of more sensitive test methods;

- Carrying out lifetime bioassays to determine the carcinogenic potential of chemicals, improving animal bioassays, and searching for more economical and rapid methods that may in some instances supplant the need for lifetime animal tests; expanding research on structure-activity relationships to begin to approach the large number of chemicals that have not been tested; and developing tests for combinations of chemicals and for tumor promoters;

- Developing improved tests to detect early biochemical, immunologic, or physiologic abnormalities associated with the development of pulmonary diseases; developing standard protocols for use in inhalation toxicology; and evaluating the utility of inhalation exposure for extrapolating dose-response results to associated risks in humans;

- Developing and validating a series of immunologic procedures to rapidly test chemicals of environmental concern, and defining a relatively simple screening battery for use in the NTP;

- Delineating the absorption, metabolism, distribution, and excretion patterns of chemicals selected for extensive toxicologic characterization by the NTP; developing a core of knowledge based on chemical class characteristics that can be used to predict the disposition of new chemicals; establishing procedures that correlate degrees of biochemical damage and rates of repair of damage with concentrations of a toxic chemical or its metabolite at particular organ target sites; and developing in vivo animal and human cell cultures that proportionally reflect in vivo metabolism in order to facilitate extrapolation of information on chemical metabolism from animals to humans; and

- Developing more effective means for estimating the hazards to human health associated with exposure to chemical environmental agents, through investigating how such evaluations should be conducted, establishing criteria, and proposing guidelines for risk assessment.

Future activities are envisioned in the areas of--

- Developing stronger links between laboratory animal studies and human epidemiologic studies in order to increase the validity of risk estimation; and

- Incorporating cardiovascular effects as an endpoint in the NTP toxicology screening program and attempting to develop in vitro assay systems that may pinpoint particular toxicologic events associated with cardiovascular diseases.

Coordinative Management Activities. These activities are basic to the NTP concept, as they provide the central functions essential to coordinating the relevant toxicology research and testing programs in the several NTP contributing agencies. Collectively they--

- Ensure that the NTP testing efforts are devoted to chemicals that are major public health concerns, that a standard base of information is provided on each chemical nominated for selection, and that each chemical selected for testing is evaluated thoroughly;

- Provide the basis for acquisition, storage, and analysis of data consistent with good laboratory practices; ensure the value of test results; and provide a management mechanism to ensure that testing is being kept on schedule and is following approved standards and methods;

- Provide a mechanism to permit orderly processing and retrieval of existing data on chemicals nominated or selected for testing by the NTP and timely announcement of NTP research results to scientific, regulatory, and societal groups;

- Develop and maintain animal resources that are of consistent high quality for the NTP chemical testing laboratories;

- Provide centralized management of chemicals tested by the NTP in order to characterize and assure the quality of chemicals; and

- Provide an effective health and safety program, covering all phases of the NTP from acquisition of the test materials to their ultimate disposal, to protect laboratory workers and the general environment from test substances that may pose toxic risks.

Table 3. RESOURCES FOR FY 1980-1984
(Dollars in Thousands)

	FY 1980	FY 1981
CDC/NIOSH	$ 5,100	$ 5,100
FDA/NCTR*	7,000	6,790
NIH Total	54,545	58,212
NCI	(43,466)	(45,686)
NIEHS	(11,079)	(12,526)

*Approximately 50 percent of the resources displayed for Chapter 18, "Prevention of Reproductive Effects Due to Workplace Hazards," are also included in resources directed to NTP.

Chapter 11

RESEARCH ON BIOLOGICAL EFFECTS OF IONIZING RADIATION

Sponsoring agency:

National Institutes of Health
National Cancer Institute

Cosponsors:

Center for Disease Control
Bureau of Epidemiology
National Institute for Occupational Safety and Health

Food and Drug Administration
Bureau of Radiological Health

National Institutes of Health
National Institute of Environmental Health Sciences
National Institute on Aging
National Institute of Dental Research
National Institute of Arthritis, Metabolism and Digestive Diseases

Initiative coordinator:

Dr. Oddvar F. Nygaard
Special Assistant to the Director for Radiation Research
Building 31, Room 10A52
Bethesda, Maryland 20205
(301) 496-9326

Chapter 11

RESEARCH ON BIOLOGICAL EFFECTS OF IONIZING RADIATION

Purpose and Rationale

The establishment of this research initiative speaks to the Federal effort to allay the growing concerns of the American public regarding the health effects of ionizing radiation. It is one piece of a larger effort. The Department has received two mandates in this area, one from the President and one from the Congress.

In May 1978 President Carter directed the Secretary to coordinate a series of studies to determine the health effects of exposure to ionizing radiation. To implement the White House directive, the Secretary established an Interagency Task Force on the Health Effects of Ionizing Radiation, which the General Counsel, Peter Libassi, chaired. This Task Force prepared its reports and disbanded.

In November 1978 a second mandate came to the Department (P.L. 95-622), directing the Secretary to establish within HEW (HHS) a "comprehensive program of research into the biological effects of low-level ionizing radiation" and to conduct an analysis and evaluation of all current Federal research into the biological effects of ionizing radiation. Committee language accompanying the enactment of this bill required the Secretary to coordinate the development of a comprehensive Federal research program in this area. The Committee on Federal Research Into the Biological Effects of Ionizing Radiation, chaired by the Director, NIH, was established to assist in these Government-wide tasks. This Committee was superseded by the Presidentially mandated Interagency Radiation Research Committee (IRRC).

Within this broader effort, the research initiative described by this proposal will serve to carry out the Departmental research program on the health effects of ionizing radiation as required by P.L. 95-622.

Nature and Magnitude of the Health Problem

Radiation as a human hazard is currently of considerable concern to the public for several reasons, including increased use of radiation in medicine and industry, growing dependence on nuclear energy, and an increase in terrestrial radioactivity brought about through the mining of uranium. There is also increased study of the exposure from weapons testing programs in the 1950's and '60's to determine whether there have been detrimental health effects on participants in the testing program and certain local civilian

populations. In addition, a potential increase in radioactive pollutants has caused concern among scientists, who recognize that radiation exposure may engender long-term health risks.

The effects of moderate and large doses of ionizing radiation (50 rads and higher) are reasonably well understood, and the dose-response relationships for a number of end-points quite well established. In terms of low dose rates and/or low total exposures to ionizing radiation, precise dose-response relationships have not been established, nor are the mechanisms well understood for the principal effects seen after low doses. In terms of human health, somatic effects of exposure to ionizing radiation are judged to be by far most important health effects when considering the increase in environmental radiation levels from human activities: medical, industrial, or military.

On the basis of data made available in 1977 in the report of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), the number of individuals in the United States who were occupationally exposed to radiation in 1970 was estimated to be 772,000, of which 454,000 were associated with the healing arts, 125,000 in the nuclear industries, and 90,000 in nonnuclear industries. Typical average doses to these individuals in rads per year were 0.045 for those employed in the healing arts, 0.98 for those working with nuclear power reactors, and 0.19 in the nonnuclear industries, with some variations over subsequent years.

The overall determination of the potential health problem requires the development of methods to ascertain with greater accuracy the levels of exposure and absorbed dose, and to improve the accuracy of risk estimates.

Effect of Initiative on the Health Problem

A strong radiation research program is required so that levels of exposure can be better ascertained, effects of radiation on cells and tissues better understood, and the accuracy of risk estimates to humans improved. The results of such research will provide a better scientific basis for efforts to reduce the exposure of humans to radiation. The results of this research are available to and in part generated by FDA in support of its responsibility to regulate electronic products and medical devices that emit ionizing radiation.

Relation to Health Research Principles

This initiative relates to three of the Health Research Principles approved by the Secretary, HHS, as underlying the Federal commitment to health research. First, it relates to the need for steady support of fundamental research to develop the knowledge base for direct attacks on health problems. The initiative will seek to elucidate the physical and biochemical mechanisms underlying the biological effects of ionizing radiation. Second, it speaks to the need to generate the knowledge base for health regulation and promotion. The knowledge developed through the initiative will help establish preventive measures and provide the science base from which to

formulate regulations as required to protect the public from radiation hazards. Finally, it is concerned with the need to sustain research capabilities. Planning for the initiative will attempt to assure that all resources required to carry out the program are available, including trained scientists, physical facilities, and funds.

Implementing Arrangements

Current Scope of Research Activities

The current HHS research activities concerning the biological effects of ionizing radiation are funded by grants, contracts, and interagency agreements, or are conducted as intramural projects. The total fiscal year 1980 expenditures of HHS agencies in this area of research are estimated at $20.3 million.

The scope of the HHS program (NIH, CDC, FDA) is as follows:

National Institutes of Health

Several components of NIH conduct or support research to provide a better understanding of the biological effects of ionizing radiation, thereby increasing the understanding of risk and injury from radiation. The major resources are directed principally toward experimental or nonhuman biological research, and a lesser amount to human studies. The Institutes involved at NIH are NCI, NIEHS, NIA, NIDR, and NIAMDD. The major elements of the NIH program are--

- Basic or fundamental studies in carcinogenesis, epidemiology, and radiobiology to determine effects as related to dosage and how these are modified by distribution over time (e.g., a single large dose vs. many small doses) and by radiation quality (low vs. high linear energy transfer [LET] radiation).

- Efforts to identify, develop, and apply methods of protecting human populations from exposure and methods to minimize human exposure when exposure is necessary.

- Efforts to further develop the technology and methodology required for analysis of the health effects of ionizing radiation.

- Mechanisms and pathways research:

  --Biological and/or physiological: To define mechanisms and pathways for the uptake, transport, distribution, metabolism and excretion of radioactive materials and products.

  --Environmental and/or ecological: To define mechanisms and pathways for the movement, transport, dissemination, dispersion, containment, and entrapment of radioactive materials and products, and their synergistic action with other environmental factors and agents.

- Resources development: Training and recruitment of skilled scientists, development of information systems, education, and demonstration activities.

Center for Disease Control

Bureau of Epidemiology. This Bureau conducts epidemiologic research concerning human health effects of ionizing radiation in various exposure settings and under field conditions. The work currently focuses on cancer occurrence in populations possibly exposed to radioactive fallout from weapons testing conducted in the past.

National Institute For Occupational Safety and Health. NIOSH is the principal Federal agency engaged in research in the national effort to eliminate on-the-job hazards to the health and safety of America's work force. The areas of research include toxicology, physical and chemical analysis, physiology and ergonomics, engineering, behavioral and motivational factors, physical agents, and epidemiology.

NIOSH is authorized to conduct research which includes study of the health effects of radiation, to develop recommended occupational safety and health standards, and to provide related technical assistance to employers and employees. In the area of ionizing radiation, NIOSH has responsibility for developing recommended occupational exposure standards for uranium mining.

Food and Drug Administration

Bureau of Radiological Health. The Food and Drug Administration is authorized to establish regulatory performance standards for radiation-emitting electronic products and medical devices, and to develop voluntary radiation guidance to assist the medical community, patients, and consumers in the prudent use of radiation-emitting equipment and products. The goals of the BRH for research into the biological effects of ionizing radiation include--

- Conduct of experimental, epidemiologic, and clinical research to assess the health effects resulting from exposures to electronic product and medical device radiation. This research includes determination of absorbed dose in biologic tissues in order to provide quantitative dose-effect information.

- Development of guidance criteria, action programs, or regulatory performance standards to control or modify radiation emissions from electronic products and medical devices.

Existing Arrangements

Coordination of radiation activities in the Federal Government is currently being effected by a number of groups with differing mandates. The Interagency Radiation Research Committee, the successor to the Committee on Federal Research Into the Biological Effects of Ionizing Radiation, was

established by the Secretary, HHS, in response to the directive from the President on February 21, 1980. The Director, NIH, has been designated Chairman of this Committee, with membership chosen from the Departments of Agriculture, Commerce, Defense, Energy, Health and Human Services, Labor, Transportation, the Consumer Product Safety Commission, Environmental Protection Agency, Federal Emergency Management Agency, National Aeronautics and Space Administration, National Science Foundation, Nuclear Regulatory Commission, and the Veterans Administration. The major components of HHS represented are the NIH, CDC, and FDA, each with one or more subordinate components.

To coordinate the formulation and implementation of Federal policy relating to radiation protection, the White House established the Federal Radiation Policy Council in February 1980 and appointed the Administrator of the Environmental Protection Agency as its first chairman. Eleven other agencies or departments, including the Nuclear Regulatory Commission and HHS, are represented on the Council.

Within HHS, two other coordinating groups should be noted. First, the Subcommittee to Coordinate Radiation Activities within the Public Health Service is a part of the broader HHS Committee to Coordinate Environmental and Related Programs. In February 1980 the Assistant Secretary for Health designated the Director of the Bureau of Radiological Health, FDA, to chair this subcommittee, which serves as a focus for information gathering and dissemination for all radiation program activities, but does not address the conduct and planning of bio-effects research. These matters fall within the purview of a second group, the one directly pertinent to this initiative: the HHS Coordinating Committee for Research on the Biological Effects of Ionizing Radiation.

Proposed Scope of Initiative Activities and Arrangements

Program planning for this radiation research initiative will be carried out by the special HHS Coordinating Committee set up for that purpose, which is made up of representatives from all collaborating components. It will be chaired by the Director, NCI, or his representative. Procedures for reporting, monitoring, and evaluating activities will be developed concurrently with the program plan. This Coordinating Committee will interact with the overall Federal research effort, as guided by the Interagency Radiation Research Committee.

Certain areas of the present research programs will be selected for intensification and expansion, specifically in basic radiation biology and human epidemiology:

- Basic studies to define the fundamental mechanisms of radiation effects. Examples of studies are:

  --Further characterization of dose-response relationships for late somatic effects induced by low and high LET radiations--for example, the investigation of cancer induction in the lung and bone by internally deposited alpha emitters--and clarification of the mechanisms at the cellular and subcellular levels.

--Additional research to define and quantify the genetic effects of external radiation exposure and of internally deposited radionuclides.

- Epidemiologic studies on the health effects of ionizing radiation in population groups. These include occupational groups, groups continuing to be studied by the Radiation Effects Research Foundation (formerly the Atomic Bomb Casualty Commission), groups exposed to nuclear fallout from weapons testing, and others who are subject to medical X-ray exposure for treatment or diagnosis.

- Additional research should determine whether, and if possible how, radiation interacts with other environmental factors and agents (including pharmaceutical) to produce mutagenic and carcinogenic effects.

- Training of persons in radiation biology, medical physics, and health physics to ensure public health and safety in the medical, industrial, and research uses of radiation.

- Resources development, including, for example, information systems, conferences, and education.

Table 4. RESOURCES FOR FY 1980-1981
(Dollars in Thousands)

	FY 1980	FY 1981
CDC/NIOSH	$ 1,600	$ 1,600
FDA/BRH	5,460	5,700
NIH Total	13,275	15,020
NCI	(11,000)	(12,400)
Other NIH	(2,275)	(2,620)

Chapter 12

POPULATION RESEARCH

Sponsoring agency:

National Institutes of Health
National Institute of Child
Health and Human Development

Initiative coordinator:

Dr. Norman Kretchmer
Director
National Institute of Child
Health and Human Development
Building 31, Room 2A03
Bethesda, Maryland 20205
(301) 496-3454

Cosponsors:

Health Services Administration
Bureau of Community Health Services

Office of Health Research, Statistics, and Technology
National Center for Health Statistics

Center for Disease Control
Family Planning Evaluation Division

Food and Drug Administration

Alcohol, Drug Abuse, and Mental Health Administration

National Institutes of Health
National Institute on Aging
National Cancer Institute
National Institute of Environmental Health Sciences
National Heart, Lung, and Blood Institute
National Institute of Neurological and Communicative
Disorders and Stroke
Division of Research Resources

Health Care Financing Administration

Social Security Administration

Chapter 12

POPULATION RESEARCH

Purpose and Rationale

Population research addresses a complex of biological, social, economic, and environmental factors that relate to reproduction and to changes in population. Investigations in population research include the biomedical study of reproductive processes in humans and animals and the development and evaluation of contraceptives. Behavioral and epidemiologic research address methods to improve the delivery of family planning services as well as determinants in fertility and population changes.

The initiative on population research is characterized by measures to foster the continuance of cooperation among the agencies involved. A main objective is to maintain progress on problems of population change and adverse reproductive outcome.

Population and population-related research is supported through seven agencies of HHS: the National Institutes of Health, Health Services Administration, Office of the Assistant Secretary for Health, Center for Disease Control, Food and Drug Administration, the Alcohol, Drug Abuse, and Mental Health Administration, and the Health Care Financing Administration. Their activities include support for basic and applied biomedical and behavioral research, operational research and evaluation studies on family planning services, demographic studies on the changes in attitudes toward fertility, and evaluation studies on the acceptability, safety, and efficacy of various methods of contraception.

Nature of the Health Problem

A significant number of unwanted births still occur among American women, especially adolescents. In 1973 an estimated 9 percent of all births to women currently or previously married were unwanted, which represents about 260,000 unwanted children. Unwanted births frequently result in financial hardships. And unwanted children often have adverse effects upon family relations, leading to adjustment problems for parents and children.

Teenage pregnancy and illegitimacy are issues of continuing concern in the United States. While adolescents' birth rates have declined recently, they are still at disturbingly high levels for the very young, whose births are the most problematic. Illegitimacy rates are high for women aged 15 to 19 and have risen for white teens. In 1976, there were 570,672 births to

women under age 20, of which 235,000 were out-of-wedlock births and 115,000 were to girls under 17. These facts have serious implications for both society and young mothers, who are poorly equipped--socially, physiologically, economically--to assume the responsibilities of parenthood. Moreover, women who have their first births when very young tend to bear additional children at a more rapid rate than those who start their childbearing later. This spacing of pregnancies is associated with additional health risks to both mothers and children.

Infertility is another health problem addressed by efforts in population research. For a variety of medical and psychological reasons, about 3 percent of all American couples in which the wife is under age 45 are involuntarily sterile or have difficulty conceiving. This represents over a million couples who are affected by infertility. From a total health perspective, the inability to regulate fertility can have consequences for both the individual and society. Infant and maternal mortality or illness and congenital defects are potential adverse health outcomes of pregnancy, and are most likely to occur when a women is in her teens or over 35, when her births are too closely spaced, or when she has already had several pregnancies. In addition to fertility, the shift in the age distribution of the U.S. population towards a greater proportion of individuals over 65 years of age is expected to have a major effect on our health care system.

Effect of the Initiative on the Health Problem

The social and behavioral sciences contribute to the improvement of family planning services and the development of population policy. Studies are concerned with the effects of social and economic policies on the birth rate, on changes in family structure, and on the changing role of men and women in society, particularly as these affect fertility and related variables, such as marriage, divorce, illegitimacy, and the forms of family planning services.

The results of research in the population sciences will bring needed improvements in all of reproductive health through the advancement of fundamental knowledge on safer and more effective methods of fertility regulation for use by both men and women, on the alleviation of infertility, on the social and behavioral factors that affect contraceptive use, and on the impact of population changes on health.

Relationship to the Health Research Principles

The initiative relates to the first Health Research Principle by encouraging and maintaining support of fundamental research on reproductive processes and on contraceptive development and evaluation. It seeks knowledge "to meet the full range of health needs and expectations" through social and behavioral sciences brought to bear on population distribution, change, and characteristics, on fertility and mortality, on marriage and divorce, and on the family.

The initiative concerns research on contraception, including clinical trials of contraceptive drugs, devices, and other methods of fertility regu-

lation, and social sciences research to assess the delivery of family planning services. These activities relate to the second Health Research Principle regarding the application of research to health services and clinical practice.

The initiative includes research on the evaluation and monitoring of the safety and effectiveness of contraceptive methods. This fulfills the needs stated in the third Principle of providing information that must underlie government regulations.

Implementing Arrangements

Current Scope of Research Activity

Organizations within HHS that have programs of population research are as follows:

- The Center for Population Research, of the National Institute of Child Health and Human Development at NIH, is responsible for the primary Federal effort in this field. Support is provided for fundamental biomedical research in the reproductive sciences relevant to problems of fertility, for development of new and improved methods of fertility regulation, for evaluation of the safety and effectiveness of contraceptive methods currently in use, and for research in the social and behavioral sciences on the reproductive motivation of individuals and the causes and consequences of population change.

- The Bureau of Community Health Services, in the Health Services Administration, funds operational research to improve, assess, and test innovative ways of delivering family planning services.

- The National Center for Health Statistics, of the Office of the Assistant Secretary for Health, conducts surveys to provide information on factors influencing trends in fertility, including family size preferences, family planning practices, and the effectiveness and acceptability of various family planning methods.

- The Family Planning Evaluation Division, of the Center for Disease Control, carries out studies to evaluate the impact of family planning strategies on the incidence of unplanned pregnancy, abortion, and mortality.

- The Food and Drug Administration sponsors or monitors the progress of research necessary to carry out its regulatory responsibilities relating to the safety and effectiveness of contraceptive drugs and devices.

The HHS agencies listed below provide funding for population-related research.

- The National Institutes of Health supports such research through--

--The National Institute on Aging: reproductive and demographic correlates of aging.

--National Cancer Institute: reproductive endocrinology and carcinogenic effects of synthetic estrogens.

--National Institute of Environmental Health Sciences: toxic effects of environmental agents on reproduction.

--National Institute of Neurological and Communicative Disorders and Stroke: reproductive neuroendocrinology.

--Division of Research Resources: general research support relevant to the population field.

- The Alcohol, Drug Abuse, and Mental Health Administration supports population-related research in the biomedical, social, and behavioral sciences through its National Institute on Alcohol Abuse and Alcoholism, National Institute on Drug Abuse, and National Institute of Mental Health.

- The Social Security Administration supports population-related research on economic and demographic interactions in the United States and the implications for the Social Security system.

- The Office of the Deputy Assistant Secretary for Population Affairs serves to coordinate population and population-related research.

- The Health Care Financing Administration sponsors research and demonstration activities focusing upon the elderly population's utilization of long-term care services under Medicaid and Medicare. These activities explore means of containing health care costs while improving the management, delivery, and quality of services.

Existing Arrangements

The Center for Population Research (CPR), National Institute of Child Health and Human Development, is designated the lead agency for federally supported research on population. In this leadership role, the CPR also serves as a resource to other agencies involved in population studies.

In addition to the CPR, there is the Interagency Committee on Population Research (ICPR), which was established by the Secretary of HEW in 1970. The ICPR's purpose is to facilitate the exchange of information among those interested in population research; to provide a means of improving coordination of research relevant to the solution of human population problems; and to analyze Federal population research activities and make recommendations on research efforts needed in the population sciences. The membership of the ICPR includes the Deputy Assistant Secretary for Population Affairs, who encourages and facilitates coordination, cooperation, and information exchange on population research and human services.

Proposed Scope of Research Activity

Reproductive Sciences. Research in the reproductive sciences will emphasize studies on infertility, the mechanism of reproductive hormone action, fertilization and implantation, and diseases and disorders of the human reproductive system. Nutrition and reproduction, aging and reproduction, and fertility and neuroendocrinology will also be emphasized.

Contraceptive Development. Studies will emphasize the development of new drugs and delivery systems and improved barrier methods. Clinical trials will be supported on new contraceptives for males, on long-acting progestins, and on antifertility methods based on periodic abstinence.

Contraceptive Evaluation. Investigations will be supported on health risks associated with the use of oral contraceptives. Particular attention will be given to risks for adolescents and risks in association with cancer and cardiovascular complications. Intrauterine devices will be studied, with attention to the relative risk of such health problems as infections of the uterus and other pelvic organs, abnormal vaginal bleeding, and infertility. Emphasis will be given to the possible long-term adverse effects of vasectomy, to studies of the long-term risks in women of tubal ligation, and to investigations to determine the current success rates in restoring fertility by reversing sterilization in men and women.

Social and Behavioral Sciences. Studies are planned on trends in fertility and related variables, on the status and roles of women, and on changes in family structure and their consequences. Other studies will provide geographic- and population-specific data on knowledge, accessibility, and use of various methods of contraception. Demographic research will be conducted on reproductive behavior and aging.

Health Services Delivery. Operational studies will be supported to improve the delivery of services in family planning. Activities will be directed toward the development and delivery of family planning information and educational materials. Services for natural family planning, infertility, and adolescents will be given special emphasis. Efforts in the next five years will concentrate upon improved patient management and community involvement, information and education systems, and the evaluation of new and existing modalities for service delivery.

Health and Social Services for the Elderly. HCFA, as part of a larger Health and Human Services long-term care initiative, is planning national surveys of the elderly institutionalized and noninstitutionalized population. The goals of this research are to obtain national estimates of the mix and extent of functional disability, utilization of health and social services, the cost and financing of services, and the supply of services from formal and informal sources.

Table 5. RESOURCES FOR FY 1980-1981
(Dollars in Thousands)

	FY 1980	FY 1981 budget
ADAMHA	$ 9,136	$10,659
CDC	250	250
FDA	148	155
HCFA	500	500
HSA	3,000	3,000
OHRST/NCHS	8,400	8,400
NIH	98,043	101,000

Chapter 13

SMOKING AND HEALTH

Joint sponsoring agencies:

National Institute on Drug Abuse, ADAMHA
National Cancer Institute, NIH

Cosponsors:

National Institutes of Health
- National Institute of Child Health and Human Development
- National Heart, Lung, and Blood Institute
- National Cancer Institute
- National Institute of Environmental Health Sciences
- National Institute on Aging
- National Institute of Allergy and Infectious Diseases

Alcohol, Drug Abuse, and Mental Health Administration
- National Institute on Drug Abuse

Food and Drug Administration

Office on Smoking and Health

Center for Disease Control
- National Institute for Occupational Safety and Health

Office of Health Research, Statistics, and Technology
- National Center for Health Care Statistics

Initiative coordinators:

Dr. Diane Fink
Associate Director for Medical
Applications of Cancer Research
National Cancer Institute
Bldg. 31, Room 11A33
9000 Rockville Pike
Bethesda, Maryland 20205
(301) 496-1316

Drs. Marvin Snyder/John Grabowski
National Institute on Drug Abuse
Parklawn Building
5600 Fisher Lane
Rockville, Maryland 20857
(301) 443-6420

Chapter 13

SMOKING AND HEALTH

Purpose and Rationale

The 1979 Report of the Surgeon General on Smoking and Health cites evidence that 345,000 premature deaths are associated with cigarette smoking each year. The annual costs of the resulting deaths and disabilities are estimated at $27 billion. Smoking is the largest preventable cause of death in America.

This initiative will be undertaken as a cooperative effort involving 12 subgroups of the U.S. Public Health Service. Six of these are institutes within the National Institutes of Health: National Institute of Child Health and Human Development (NICHD); National Heart, Lung, and Blood Institute (NHLBI); National Cancer Institute (NCI); National Institute of Environmental Health Sciences (NIEHS); and National Institute on Aging (NIA).

The other partners are the Alcohol, Drug Abuse, and Mental Health Administration's National Institute on Drug Abuse (NIDA); the Food and Drug Administration (FDA); the Office of Smoking and Health (OSH); the Center for Disease Control (CDC) including the National Institute for Occupational Safety and Health (NIOSH); and the National Center for Health Statistics (NCHS), which is a part of the Office of Health Research, Statistics, and Technology.

The initiative addresses both biomedical and behavioral research related to smoking and health. The health problems it addresses are the cardiovascular, pulmonary, and neoplastic diseases and the reproductive and developmental disorders attributable to cigarette smoking, as well as basic research questions in biology, toxicology, immunology, and epidemiology. Further studies will examine why people begin to smoke, what maintains the behavior, why it is difficult to stop smoking, and what accounts for the high number of people who relapse to smoking. Finally, research must evaluate the direct effects of smoking on other persons in the immediate environment.

Nature of the Health Problem

Smoking and other forms of tobacco use have major public health consequences in the United States and elsewhere. Health effects of smoking have been demonstrated for cancer, heart and pulmonary disease, pregnancy outcome, and other disorders. Evidence indicates that the total number of smokers has decreased, but that 54 million Americans continue to smoke.

Over the years since the first reports relating health effects to smoking, the proportion of individuals smoking lower tar and nicotine cigarettes has increased. Evidence suggests that the way the smoker uses these cigarettes has changed. The overall health effects of these changes are yet to be determined.

Relationship to the Health Research Principles

The initiative embodies the Health Research Principles in the following manner:

- The effects of smoking on public health make smoking directly pertinent to the Department's health mission. Because our ability to improve public health in relation to smoking depends on knowledge available, the accomplishment of the HHS mission is facilitated by basic and applied biomedical and behavioral studies pertinent to the health effects of smoking, and by studies on the toxicology, physiology, epidemiology, psychology, and sociology of smoking.

- The need to facilitate the application of fundamental knowledge to solution of specific health care problems (another of the health research principles) is also provided for in the initiative. For example, the initiative includes educational and behavioral intervention programs designed to take advantage of indications that health risks associated with smoking may be reversible. There will be studies to develop and improve methods to prevent the onset of smoking and tobacco use; to assist the smoker in breaking the habit; and maintaining cessation. Such activities can be expected to contain health costs.

Related Activities

An ad hoc Interagency Discussion Group on Smoking and Behavior has been formed and has met six times since September 1979. During half of these meetings, a member selected from one of the organizations has presented a review of his/her organization's research program. During alternate meetings, various researchers have given state-of-the-art presentations in high-interest areas such as smoking prevention in children and adolescents, and the effects of smoking by pregnant women on the fetus. These meetings have fostered better communication among organizations, helping to avoid both overlap and gaps in the programs and encouraging the active informal relations needed for an effective interagency research program.

Additionally, the NHLBI is mandated by the Congress to coordinate all research on heart, lung, and blood diseases among Federal agencies through the Interagency Technical Committee (ITC), which has a subgroup that focuses on smoking and health. Its members are conducting a prototype media and community project designed for medium and small television markets. Further, the members are in the process of developing a continuing education program to help physicians help their patients stop smoking and to study the impact of smoking policy on behavior and attitudes. A compendium of research

activities on smoking and on the heart, lung, and blood has also been completed. A biomedical subgroup of the ITC has conducted a TOXLINE search, and a conference on carbon monoxide and the cardiovascular system may be planned.

The Office on Smoking and Health, OASH, PHS, which serves as a focal point for all PHS activities related to smoking, developed the 1980 Surgeon General's Report on the health consequences of smoking for women. More recently the Office conducted a working meeting on research needs on low yield cigarettes in which all the organizations were involved. The results of that meeting, including detailed research recommendations, form the body of the 1981 report of the Surgeon General.

Under the joint sponsorship of ADAMHA and NIH, a conference on Smoking and Behavior was conducted by the Institute of Medicine, National Academy of Sciences, September 27-28, 1979. This conference was part of a series of IOM conferences on health and behavior. The report from this meeting highlighted several topics requiring further research.

The reports and recommendations from the Conference on Smoking and Behavior, and the Workshop on the Low Yield Cigarette, will be used by the organizations cooperating in this initiative to further develop and coordinate their research programs.

Scope of Current and Planned Research Activity

The activity calls for two major activities during the next twelve months:

- Cooperative information exchange and joint discussions of HHS activities related to Smoking and Health.
- Development of a biomedical and behavioral research strategy for all involved agencies in the area of Smoking and Health.

Role of the Public Health Service Subgroups

NICHD Role in Smoking-Related Research

In keeping with the essential goal of the NICHD to assure that all children are provided the opportunity for a healthful and productive adulthood, the NICHD supports biomedical and behavioral research on the effect of smoking on development, and on the prevention of smoking and other behavior harmful to health. Program aspects include:

- Predisposing personal and social characteristics that are antecedents to smoking and other behavior harmful to health, as well as influences, conditions, and behavior that lead to habitual smoking.
- Factors that may serve to deter the onset of smoking, such as strategies to assist young persons to resist peer pressure and media appeal and to realize their responsibility for maintaining health.

- Identification of risk for perinatal losses or damage in offspring of women who smoke during pregnancy; also definition of maternal and neonatal effects resulting from maternally inhaled tobacco smoke, including general studies on lactation and breast feeding and specific effects on adequacy of milk secretion.

The NICHD portion of this initiative on smoking and health is part of Institute efforts to conduct and support (1) investigations of psychosocial adaptation of the child and the role of the family in the development of positive attitudes toward health-promoting activities; and (2) investigations of the interaction of environmental and maternal factors on fetal development.

NHLBI Role in Smoking-Related Research

The NHLBI is interested in expanding research activities on the effects of tobacco smoking on the cardiovascular system, on the respiratory system, and on the hemostatic properties of the blood. The research mission includes:

- The function of the sympathetic nervous system with respect to cardiovascular events.
- Normal and ischemic cardiac conduction, metabolism, and function.
- Coronary, cerebral, peripheral and pulmonary circulation.
- Malignant hypertension.
- The pharmacokinetics of appropriate smoke components.
- Mechanisms pertinent to atherogenesis.
- Effects of lipoprotein metabolism.
- Platelet physiology and the thrombotic process.
- Interactions between chemicals in smoke and hemoglobin structure and function.
- Mechanisms responsible for development of chronic obstructive lung disease.
- Acute or chronic toxicity of gaseous and particulate components in cigarette smoke in relation to cardiovascular or respiratory disease.
- Smoking avoidance, cessation, and long-term maintenance of cessation, particularly in those at high risk of cardiovascular or respiratory disease.

NCI Role in Smoking-Related Research

The NCI is responsible for epidemiologic, toxicologic, behavioral, and

social research as well as demonstration activities to identify the cancer risks associated with smoking and for the development of strategies for prevention and cessation. Studies include:

- Research projects aimed at understanding the nature of behavioral dependence on smoking and its development in high-risk subgroups that are not decreasing smoking behavior, such as adolescents, females, nonwhite males, and workers exposed to known or suspected carcinogens.

- Evaluation of smoking prevention/cessation methods, especially among high-risk groups--as mentioned above.

- Community demonstration and education programs to affect changes in smoking patterns, including findings from research on self-help technique and other programs.

- Communication and education projects to determine the most effective means to provide information on smoking effects to the public.

- Education of graduate and postgraduate health professionals on the public health significance of smoking and smoking intervention. These activities will enable health professionals to inform their patients and other members of the public on smoking prevention/cessation strategies.

- Epidemiologic studies to assess health effects due to changing smoking habits including other uses of tobacco.

- Toxicologic studies to determine promoting and carcinogenic effects of constituents in both particulate and gaseous phases of cigarette smoke.

- Search for animal models better suited to examine cancer-related health effects of smoking.

- Search for (1) biologic markers or other indicators to identify individuals at unusually high risk for the development of cancer, and (2) the means to detect preneoplastic or early neoplastic changes.

NIEHS Role in Smoking-Related Research

Through NIEHS's extramural activities and the National Toxicology Program (NTP), studies are being conducted to determine the effects of smoking as a cofactor of environmental pollution. Further, the NTP is developing test methods to determine the effects of chemicals in various organic systems as well as reproduction, mutagenesis, and carcinogenesis. These tests are applicable to the components of cigarettes.

NIA Role in Smoking-Related Research

The NIA will be undertaking studies to determine smoking patterns and

effects on older individuals through the following studies:

- The followup of 14,000 individuals from the original cohort (original sample = 21,000 individuals) of the Health and Nutrition Examination Survey (HANES) to determine changes in smoking patterns over the course of a decade.

- The determination of the relationship of psychologic factors, the maintenance and cessation of smoking and amount of smoking using data from the Normative Aging Study. Longitudinal studies on the medical outcomes of smoking cessation, such as changes in pulmonary function, will be conducted employing this sample.

NIAID Role in Smoking-Related Research

The NIAID is interested in the two effects of tobacco and its products on the immune system. As antigens, tobacco and its products can interact with the immune system to induce specific responses evidenced by production of specific antibody or sensitized cells. As irritant, pharmacologic, and toxic agents, they can interact and interfere with the functional ability of immunocompetent cells.

NIDA Role in Smoking-Related Research

Smoking presents two categories of behavioral problems as a form of drug use. One category is represented by the explicit problem (inherent in all forms of habitual drug self-administration) of tobacco use itself which presents difficulties in the context of establishing and maintaining smoking cessation. Second, there exist the clear detrimental short- and long-term physical and behavioral health consequences of smoking. Concurrently, there are, as with other substance use/abuse problems, drug-behavior-environment interactions, the examination of which will contribute to better understanding of maladaptive drug use generally. NIDA will continue to pursue research concerning smoking in terms of:

- The behavioral, psychological, psychosocial and pharmacological factors that lead to the acquisition, maintenance, and cessation of smoking.

- The behavioral pharmacology of the dependence, including the abuse potential and reinforcing efficacy of tobacco/nicotine.

- The behavioral pharmacology of dependence upon tobacco, including the potential for abuse and the capacity of its constitutents, such as nicotine, to reinforce dependence.

- The development of new and innovative procedures for use with individuals and large groups, such as behavior modification/therapy and pharmacotherapeutic interventions, to achieve and maintain abstinence.

- The biobehavioral basis of tobacco, nicotine, and related substance dependence, including basic studies, search for nicotine receptors in

the central nervous system, and biological assay techniques for detecting nicotine in body fluids.

- The role of smoking as a gateway activity to other forms of harmful drug use/abuse behaviors.

FDA Role in Smoking-Related Research

The FDA is currently involved in a study to determine whether ethyl alcohol has a synergistic effect on chromosome damage when combined with a known mutagenic substance from tobacco smoke.

OSH Role in Smoking-Related Research

OSH is responsible for ensuring that all Public Health Service smoking and health-related programs are consistent with departmental policies and goals. The Office serves as a clearinghouse for scientific and technical information and data related to smoking and health. In addition, the Office coordinates research findings and survey data from agencies, prepares annual scientific reports to the Congress, and provides a departmental liaison to nongovernment groups involved in smoking research.

CDC/NIOSH Role in Smoking-Related Research

CDC. Has undertaken or is planning to conduct the following smoking research and demonstration activities:

- Develop and test smoking program protocols that can be used by official, community, and voluntary organizations in implementing action programs for youth on smoking and health.

- Develop health education techniques by which smokers can assess their level of health risk and then participate in appropriate educational intervention activities.

- Support and evaluate intervention projects to prevent smoking and misuse of alcohol by children and adolescents in school and community settings.

NIOSH. Smoking and occupational exposures both contribute to the development of certain diseases. NIOSH has identified at least six different mechanisms by which smoking may act with physical and chemical agents in the workplace to produce or increase adverse health effects. Several of these may operate simultaneously.

Where possible in conducting epidemiologic studies and health hazard evaluations, NIOSH collects data on smoking as a contributing or confounding variable. Analyses of these data may uncover other mechanisms by which smoking and workplace exposure interact.

NCHS Role in Smoking-Related Research

The NCHS has regularly been assessing through several surveys the current smoking patterns of adults. It is also undertaking a longitudinal study on the changing patterns of smoking. Its surveys represent the major government resource for evaluating smoking trends and the relationship between smoking and illness in the United States.

New Arrangements

In summary, the initiative will have as its goals the coordination of Department research on the health effects of smoking and the development of an appropriate research strategy. Success will depend upon continued cooperative interaction among the twelve organizations involved. Such collaborative arrangements expand significantly the opportunities to gain the necessary knowledge base to deal effectively with the public health problems associated with smoking and tobacco use.

Jointly sponsored scientific seminars and conferences will be held on a regular basis and will involve the participating organizations and extramural scientists. Where appropriate, some or all of the participating organizations may jointly solicit, fund, and manage projects of mutual interest. Regular working meetings of the participating organizations are planned through the newly established Interagency Coordinating Committee.

Table 6. RESOURCES FOR FY 1980-1981
(Dollars in Thousands)

	FY 1980	FY 1981 Budget
ADAMHA/NIDA	$ 2,410	$ 3,200
CDC/BHE	2,000	2,000
NIH Total	16,685	16,900
NCI	(3,850)	(4,010)
NHLBI*	(10,600)	(10,600)
NICHD	(2,235)	(2,290)

*Figures reflect Smoking and Health.

Chapter 14

ALZHEIMER'S DISEASE AND THE DEMENTIAS OF AGING

Sponsoring agency:

National Institutes of Health
National Institute on Aging

Cosponsors:

Alcohol, Drug Abuse, and Mental Health Administration
National Institute of Mental Health

National Institutes of Health
National Institute of Neurological and Communicative Disorders and Stroke
National Institute of Allergy and Infectious Diseases

Initiative coordinator:

Dr. Robert N. Butler
Director
National Institute on Aging
Building 31, Room 5C02B
Bethesda, Maryland
(301) 496-9265

Chapter 14

ALZHEIMER'S DISEASE AND THE DEMENTIAS OF AGING

Purpose and Rationale

Alzheimer's disease and the dementias of aging are not inevitable consequences of growing old. They represent pathologic states subject to investigation, elucidation, and treatment.

The proposed initiative on Alzheimer's disease and the dementias of aging will bring together the broad range of resources of the National Institute on Aging (NIA), the National Institute of Mental Health (NIMH), the National Institute of Neurological and Communicative Disorders and Stroke (NINDS), the National Institute of Allergy and Infectious Diseases (NIAID), and in the future, potentially, the National Institute for Occupational Safety and Health (NIOSH), in a collaborative effort that has as its ultimate goals the prevention, specific diagnosis, and treatment of these disorders.

Nature of the Health Problem

The NIA, NIMH, NINCDS, NIAID, and NIOSH feel that the epidemic proportions of the medical, social, and economic problems presented by Alzheimer's disease and the dementias of aging mandate this effort.

- Approximately 1 million people in the United States over 65 suffer severe dementia, with global intellectual deterioration and inability to carry out the normal tasks of daily living, while an additional 2 to 3 million persons are mildly or moderately affected.

- Chronic dementias account for about 50 percent of nursing home admissions, at an estimated cost of $6 billion annually.

- Loss of productive members of society, disruption of families, and loss of human dignity are among the incalculable costs of chronic dementia.

- Demographic studies point to a rapidly escalating problem. By the year 2030 the population over 65 will have more than doubled and the annual cost of chronic care will be $30 billion, eight times the total amount now spent on all medical and mental health research.

- A 10 percent reduction in nursing home admissions could cut institutional costs by $1 billion annually, yet in 1977 less than 0.2 percent of the $24 billion spent by the Federal Government for health services to the elderly went to research on chronic dementia.

Effects of the Initiative on the Health Problem

The ultimate goals of prevention and treatment will be pursued through a cooperative effort by the NIA, NIMH, NINCDS, NIAID, and potentially NIOSH to accomplish the following seven basic objectives:

- Increase the science base of fundamental knowledge about Alzheimer's disease and the dementias of aging through basic science--clinical, epidemiologic, and behavioral;
- Increase the base of fundamental knowledge about service and support systems required for those affected by the dementias of aging, through behavioral and service system research;
- Rapidly translate basic research findings pertaining to treatment into carefully controlled clinical studies, and rapidly translate service system research into improved health and social service structure, delivery, and coordination;
- Develop reliable and accurate methodology for diagnosis so that treatable dementias can be distinguished from others presently nontreatable;
- Integrate new technology into basic and clinical research, diagnosis, and treatment;
- Disseminate research, diagnostic, and therapeutic information to the general public and to the medical and scientific communities; and
- Develop centers for training and excellence in the study of chronic dementia to provide continuing leadership and innovation in the objectives outlined here.

Relationship to the Health Research Principles

This initiative relates to the first Health Research Principle in its emphasis upon development of new knowledge through fundamental research. It relates to the second Health Research Principle by serving to apply fundamental knowledge to clinical practice in order to improve health care within a specific category of disease. It also relates to the third Principle, by seeking to provide knowledge to institutions and individuals for use in health promotion and disease prevention.

Implementing Arrangements

Current Scope of Research Activity

The NIA conducts research on the basic science and clinical aspects of regional brain metabolism, neurochemistry, and pharmacology, in aging animals and man. It is developing, with the NIMH, neuropsychiatric tests and computerized methods of diagnosis. Epidemiologic studies to define prevalence, incidence, and risk factors are under way with the NIMH and with the NINCDS,

and the role of vascular disease on the dementias is being examined as part of a long-term clinical study in collaboration with the National Heart, Lung, and Blood Institute and NINCDS. The NIA plans to develop large population "laboratories" (with some base in the community) and to do collaborative epidemiologic studies with NIOSH to investigate possible occupational factors in dementia. In addition, the NIA supports research in neurochemistry and morphology; development of noninvasive monitoring techniques for measuring brain metabolism and microcirculation; epidemiologic studies of genetic, environmental, and metabolic risk factors; and programs in clinical and research training.

The NIMH has evolved collaborative efforts with the NIA, NINCDS, and the National Institute on Alcohol Abuse and Alcoholism to develop neuropsychological diagnostic instruments for distinguishing various types of dementias and depression from dementia. It has developed, with the Office of the Assistant Secretary for Health, sensitive methods of measuring aluminum, a neurotoxin, and plans for patient testing. It collaborates with the NINCDS on "slow virus" research and with the University of Colorado (NINCDS-funded) and the University of Stockholm to study neuroplasticity. It conducts studies in pharmacology, neurotransmitters, brain peptides, and the role of toxic substances. It plans to explore pharmacologic and develop behavioral techniques to modify intellectual impairment.

The Institute also supports basic and applied clinical studies pertaining to etiology, epidemiology, and assessment; research in psychopharmacology; investigation of potential therapeutic and preventive behavioral modalities; services research and analysis; and programs in clinical and research training. Partly in collaboration with the NIA, epidemiologic studies seek a better understanding of varying rates of altered brain function in community-dwelling aged.

The major research effort of the NINCDS is to define etiology and pathogenesis in these conditions. The Institute conducts clinical research projects assaying neurotransmitters and their metabolites; therapeutic trials of promising pharmacologic agents; epidemiologic studies of well-defined populations to determine prevalence, incidence, and possible associated risk factors; and investigation of the role of slow viruses in chronic dementias by development of *in vitro* methods of diagnosis and by major epidemiologic studies to determine a possible viral etiology.

The NINCDS supports research in neurochemistry, neural membranes, neurotransmitters, and the putative role of slow viruses. With the NIMH, it supports two tissue banks to provide an adequate supply of brain tissue for future research. However, the tissue banks are for Huntington's disease, multiple sclerosis, and schizophrenia. A new bank is needed for research on the related dementias of aging. NINCDS supports research and clinical training and has initiated the NIH program on positron emission tomography (PET) scanning with awards to seven institutions.

The NIAID conducts and supports research concerned with the biology, epidemiology, prevention, and treatment of latent and slow viruses as they pertain to diseases in man and in animal models that mimic human conditions. In March 1977 the NIAID cosponsored with other NIH Institutes a research

conference on persistent viral infections. The NIAID Virology Task Force has an 18-member panel on such infections, and its deliberations and recommendations are contained in the 1979 Task Force Report. Additional conferences and workshops on various aspects of persistent virus infections have also been supported.

In the area of technology transfer, the NIA, NIMH, and NINCDS jointly sponsored two conferences at NIH: in July 1977, the workshop "Conference on Alzheimer's Disease: Senile Dementia and Related Disorders," and in December 1978, "The Clinical Aspects of Alzheimer's Disease and Senile Dementia." These provided an opportunity for biomedical scientists and clinicians to participate in exchange of information regarding research, diagnosis, and treatment of dementias. Resulting publications allowed those unable to attend the conferences to be informed of the proceedings. In July 1978 the NIA and the Fogarty International Center sponsored a consensus development meeting on "Treatable Brain Diseases in the Elderly," where experts in medical fields assembled to exchange information and develop a consensus document about definition, diagnosis, and treatment to be circulated throughout the medical community. In March 1979 the NINCDS sponsored a workshop on "Neurosecretion and Brain Peptides: Implications for Brain Function and Neurological Disease," at which research prospects for understanding the degenerative neurological diseases of late life were considered by clinical investigators. In October 1979 the Neuroscience Research Program Associates of M.I.T. devoted a meeting to the subject of dementia and reported that dementias provided a unique opportunity to study the relevant neurobiology and molecular neuropathology.

Proposed Scope of Research Activity

Current work on Alzheimer's disease and the dementias of aging will be extended and expanded as described below to achieve the objectives of this initiative. Each Institute will conduct or support work in these areas unless otherwise notified.

Etiology and Pathogenesis. Prevention and treatment of Alzheimer's disease and the dementias of aging will largely depend on understanding the cause and mechanism of the disease process.

- Neurochemistry: Further biochemical, morphologic, and pharmacologic elucidation of the pathology of the chronic dementias can direct rational therapeutic intervention. Current work in neurotransmitter deficits will be extended with therapeutic trials aimed at replacement therapy.

- Cerebral circulation and metabolism: New in vivo methods will examine local brain metabolism in man, evaluate specific pharmacotherapeutic regimens, and offer the potential of differentiating among the treatable and now nontreatable dementias. Retrospective and prospective studies will identify risk factors in dementias produced primarily by multiple cerebrovascular infarcts in elderly volunteers and patients. This information will assist in the improvement of early diagnosis.

- Neuroendocrinology: The role of brain peptides and hormones in regulating a complex variety of physical and psychological functions, particularly in the brain, will be extended and applied to the dementias.

- Neuroplasticity: The reestablishment of neural connections, known as neuroplasticity, offers the biological opportunity for return of lost function, and its role in learning and memory will be emphasized. The conventional view that the degree of dementia is proportional to the number of plaques, neurofibrillary tangles, and loss of neurons is being challenged. The use of computer technology permits a more accurate count of neurons, with the resulting view that the number of neurons in patients with Alzheimer's dementia do not differ from the age-matched controls.

- Immunology: Rational therapeutic and preventive stratagems will be pursued in further studies of the now poorly characterized decline in immune function with age and its role in preventing the brain from protecting itself against external invasion of a noxious agent, activation of a latent agent, and autoimmune brain damage.

- Virology: The demonstration that at least two human spongiform encephalopathies, Kuru and Creutzfeldt-Jacob disease, are caused by transferable or atypical slow or latent viral-like agents will be expanded to explore the possible role of a latent or slow virus in chronic dementia. This will require an expansion of the research on the biology of slow viruses. (The major contribution of NIAID will be in the field of virology.)

- Genetics: The precise role and mode of inheritance of Alzheimer's disease will be further defined through studies of an observed familial clustering of some forms of the disease and an increased association with chromosomal abnormalities and hematologic cancer.

- Animal models and brain banks: Any effort to define mechanisms, diagnoses, and treatments will require animal models and tissue and fluid from affected humans. The necessary research to develop these models will be undertaken and mechanisms sought for tissue and fluid storage.

Epidemiology. Almost all diseases have or are associated with specific epidemiologic patterns, yet none has emerged so far in the dementias. Continued and expanded studies of hospital- and community-based populations will be conducted to identify risk factors and to plan effectively for appropriate medical and mental health services. Survey instruments for case detection and followup are being tested. NIOSH has indicated an interest in this activity.

Behavioral and Social Research (NIMH). Improvement in quality of life will result from an understanding of the behavioral expression of dementias of aging and associated social problems. The following topics will be extensively studied: expression and etiologic factors of various lifestyle

phenomena; models for alternatives to institutionalization; interaction between formal and informal service systems; integration of community mental health programs; and models for continuity of care and delivery and for coordination and structuring of service systems.

Diagnosis. More sensitive and reliable techniques to distinguish treatable patient populations (20 percent of cases) will be sought. Refinement and validation of current diagnostic techniques and development of new techniques and methodologies will be pursued so that accurate diagnosis can ensure proper treatment.

Treatment and Management. The ultimate goal is to arrest the disease process and alleviate suffering. The identification of biochemical, endocrinologic, metabolic, or immunologic abnormalities, or of a viral agent, in presently nontreatable dementia will offer potential for rational pharmacotherapeutic intervention. Dietary intervention will open the field of nutritional therapy of dementia to exploration. Behavioral modes of treatment will be studied systematically. Existing therapeutic agents will be tested for efficacy in carefully controlled studies, and basic research findings will be translated into clinical trials. Neuroprostheses for incontinence, hearing, speech, and memory will be developed and tested.

Resources. Technological advances will be integrated into efforts to define etiology and pathogenesis, refine diagnosis, and develop treatment. Researchers using PET scans, a sensitive noninvasive methodology, will closely monitor regional metabolic, chemical, and circulatory changes in the brain, will correlate them with changes in cognition, and will evaluate brain responses to therapeutic regimens.

Technology Transfer. Research, diagnostic, and therapeutic information will be disseminated to the general public as well as the medical and scientific communities, through journals, monographs, and such conferences as those held in 1977, '78, and '79.

Training. Centers of excellence for training in the study of the dementias of aging will be created where teams of investigators focus on these problems and basic and clinical research training are provided.

The initiative on Alzheimer's disease and the dementias of aging will strengthen collaboration among the NIA, NIAID, NIMH, NINCDS, and potentially NIOSH. It will provide a framework and act as a catalyst for these Institutes as they strive toward ultimate goals of prevention and treatment.

Table 7. RESOURCES FOR FY 1980-1981
(Dollars in Thousands)

	FY 1980	FY 1981 Budget
ADAMHA/NIMH	$ 4,800	$ 5,100
NIH Total	11,073	13,933
NIA	(3,793)	(4,343)
NIAID	(1,990)	(2,135)
NINCDS	(5,290)	(7,455)

Chapter 15

HEALTH CARE TECHNOLOGY ASSESSMENT

Sponsoring agency:

Office of Health Research,
Statistics, and Technology
National Center for
Health Care Technology

Initiative coordinator:

Dr. Seymour Perry
Director
National Center for Health
Care Technology, OHRST/OASH
Parklawn Building, Room 17A-32
Rockville, Maryland 20857
(301) 443-4097

Cosponsors:

Office of the Secretary

Office of the Assistant Secretary for Health

Office of Health Research Statistics, and Technology
National Center for Health Statistics
National Center for Health Services Research

National Institutes of Health

Alcohol, Drug Abuse, and Mental Health Administration

Center for Disease Control

Food and Drug Administration

Health Services Administration

Health Resources Administration

Health Care Financing Administration

[NOTE: A number of non-HHS agencies that may also participate are listed in the initiative.]

Chapter 15

HEALTH CARE TECHNOLOGY ASSESSMENT

Purpose and Rationale

This research initiative brings together a number of health agencies and offices of the Department of Health and Human Services (HHS) in an important new effort to ensure effective assessments of high-priority health care technologies. Technology assessments take into account safety, efficacy, cost, cost-effectiveness, and actual or potential social, economic, and ethical implications of particular health care technologies. These assessments may be broad in scope and examine many aspects of a particular technology, or they may be limited in scope and focus on a particular aspect of a technology.

The lead agency for this effort is the National Center for Health Care Technology (NCHCT or Center), a part of the Office of Health Research, Statistics, and Technology (OHRST), in the Office of the Assistant Secretary for Health (OASH). The Center was established to conduct or sponsor assessments of high-priority emerging, new, and established technologies. In discharging this responsibility, it utilizes its own staff, draws on the strengths of the other PHS agencies, and collaborates with the National Council of Health Care Technology (Council). In these activities, the Center fosters broad and open participation by those individuals and groups with pertinent knowledge of or interest in the particular technology under consideration.

Goals

The NCHCT is not a regulatory agency, nor are its activities aimed at determining or interfering with the practice of medicine. Rather, the Center is a knowledge development agency with two primary functions:

- To develop evaluative information about health care technologies that is needed by various decision-makers in the public and private sectors, such as providers of health services; the academic community; industry; agencies that have reimbursement, health planning, quality assurance or related responsibilities; the Congress; and the general public.

- To ensure that such information is disseminated as expeditiously as possible in the most useful form. This evaluative information is disseminated widely through a variety of pathways, including the publication of monographs and reports, the National Library of Medicine, and sponsorship of and participation in meetings with professional, governmental, and other groups.

Health Care Technology Assessment

A major responsibility of the Center--and the main objective of this initiative--is to facilitate, sponsor, conduct, and coordinate the assessment of high-priority health care technologies. These assessments are performed by a variety of researchers within and outside the Government. The focus is on analyses of the medical and scientific bases for selected technologies, as well as the impacts of these technologies on society, the individual patient, the health care delivery system, and public and private health care financing agencies and organizations such as the Health Care Financing Administration (HCFA) and Blue Cross/Blue Shield Associations.

Cooperating Organizations

The principal mechanism through which the NCHCT coordinates the Department's activities in health care technology is the HHS Technology Coordinating Committee (TCC), composed of representatives from all Public Health Service (PHS) agencies and HCFA. The Committee serves as a forum to address health care technology-related matters.

The Committee also includes liaison representation from the Office of the Secretary, OASH, and OHRST. Other Federal departments, agencies, and offices that have an interest in health care technology and are also represented on the TCC include the National Institute of Handicapped Research in the Department of Education, Office of Science and Technology Policy (OSTP) in the Executive Office of the President, the Congressional Office of Technology Assessment (OTA), Veterans Administration, and Department of Energy. Other Federal agencies, such as the National Aeronautics and Space Administration and the National Bureau of Standards, may also be invited to participate in the TCC.

The NCHCT works closely with these agencies, as appropriate, in conducting technology assessments and in identifying opportunities for collaborative research. The Center seeks to engage the assistance of appropriate agencies in the technology assessments which it conducts and, whenever possible, complements or cosponsors assessments that are being carried out by other Federal agencies. Consistent with its mandate, however, the NCHCT is responsible for conducting or sponsoring full, multifaceted assessments of particular high-priority technologies, including evaluations of their medical and scientific aspects, when other Federal agencies are unable to participate in such assessment activities because of resource constraints or other reasons.

The Council is the Center's principal advisory body. It comprises 18 persons from the private sector who are distinguished in various pursuits related to health care and health care technology, plus ex officio representatives of Government health agencies and programs. The Council is charged with a number of important review and advisory functions in conjunction with the programs of the NCHCT.

Nature and Magnitude of Health Problems Addressed

Prior to the establishment of the NCHCT, there was no formal, centralized mechanism for conducting, sponsoring, and coordinating comprehensive

assessments of emerging, new, or existing health care technologies, or for informing interested parties about the safety and efficacy of particular technologies and their economic, ethical, and other social impacts. There has been no formal mechanism in either the Government or the private sector to provide the kind of evaluative information the Center is charged to develop. Accordingly, technologies have often diffused into health practice in the absence of sound data on safety and efficacy, and outmoded health care technologies have usually been abandoned only after collective experience has suggested that they are ineffective or hazardous. Firm estimates on resultant health care problems and unnecessary costs are not available, but they are clearly substantial.

Anticipated Health Benefits

Technology assessments have the potential to improve the quality of care by encouraging the appropriate use of health care technologies and by discouraging the continued use of technologies considered unsafe or ineffective. At the same time, the assessments conducted by the NCHCT will provide important information to Health Systems Agencies (HSAs), Professional Standards Review Organizations (PSROs), and others that can help the Department and the Nation achieve desired objectives in health planning, cost containment, and improved health care.

Relationship to Health Research Principles

The process of performing health care technology assessments clearly supports the second Health Research Principle, "To improve the quality of health care, prevent disease, and contain health care costs, the health system requires . . . the support of applied, problem-oriented health and health services research. . . ." Also pertinent is a subordinate element of that principle: "Further research and evaluation are needed to determine the most efficient and effective methods of technology transfer." The totality of the NCHCT's intramural and extramural programs for assessments, research, demonstrations, and evaluations in the field of health care technology may be viewed as directly related to that Health Research Principle and the Health Care Technology Assessment research initiative.

Implementing Arrangements

Scope of Current Research Activity

The NCHCT has initiated its extramural program for assessments, research, demonstrations, and evaluations in the field of health care technology and is also establishing its intramural research program. The Center has developed a tentative Technology Assessment List which sets forth the health care technologies it plans to address during the next few years. The list includes all of the diagnostic and therapeutic technologies that the Council has identified as priorities for assessment by the NCHCT, as well as a number of other topics recommended to the Center by the TCC, the Assistant Secretary for Health and Surgeon General, and others.

Although the list is a working guide for structuring the Center's assessment activities, it must of necessity remain flexible and open to change. The NCHCT's current assessment priorities may shift to accommodate the assessment of additional high-priority technologies identified at a later date by the Council, the Secretary, the Assistant Secretary for Health and Surgeon General, the Congress, industry, medical and other professional groups, and others. The list will be updated periodically to reflect the Center's budget. The current list includes the following technologies:

*Maternal serum alpha-fetoprotein (MSAFP) test for detection of fetal neural tube defects

*Coronary artery bypass surgery

*Total knee replacement

Total hip replacement

*Ultrasound for cardiac diagnosis

*Cerebral artery bypass surgery for treatment of stroke

*Positron emission transaxial tomography (PETT)

*Dental X-rays

*Cesarean section and electronic fetal monitoring

*Renal transplant and dialysis for end-stage renal disease (ESRD)

*Heart transplants

Computerized tomographic (CT) scanning of the head and body

Cardiac nuclear imaging

Barium enema

Skull X-rays

Total parenteral nutrition

Pap test in cervical cancer screening

Endoscopy in upper GI hemorrhage

Psychotherapeutic techniques

*High-priority technology; assessment recommended by the Council.

Nuclear magnetic resonance

Electroencephalography

Neonatal intensive care units

Neurosurgery for mental disorders

Continuous flow analysis/multianalyses

Each of the technologies listed above is considered a significant candidate for assessment, according to criteria set forth in Public Law 95-623, the Health Services Research, Health Statistics, and Health Care Technology Act of 1978. These criteria include potential and actual risk/benefit, potential and actual cost/benefit, stage of development, and potential for abuse, such as overuse and inappropriate use. The final selection of technologies for assessment is made, however, with the advice of the Council, which assists the NCHCT in establishing the priorities for technology assessment. The Council has developed written criteria for identifying high-priority technologies for assessment by the Center.

The Center also has developed and begun to implement the methodology and format that will be followed in performing technology assessments. A cardinal principle is that broad and open participation will be encouraged and direct Federal involvement minimized.

The NCHCT has initiated full, multifaceted assessments and is collaborating with other agencies (through analyses of safety, efficacy, and cost-effectiveness, and of social, economic, and ethical impacts) in the assessment of several high-priority health care technologies. Examples of the latter include: the MSAFP test for detection of fetal neural tube defects; dental X-rays; renal dialysis and transplantation in ESRD; heart transplants; coronary artery bypass surgery; and CT scanning. Subcommittees of the TCC are well along in planning the assessments of most of these technologies.

In July 1980 the NCHCT and Food and Drug Administration (FDA) cosponsored as national educational conference on MSAFP, in collaboration with the NIH, Center for Disease Control (CDC), Health Services Administration (HSA), and HCFA. Conferees examined the state-of-the-art of this technology (and other technologies, such as amniocentesis and sonography, used in screening for fetal neural tube defects) and explored the major medical, scientific, social, ethical, and economic issues associated with MSAFP screening. The FDA is planning to release the MSAFP reagent test kits for marketing in the United States in calendar year 1981 and will follow the use of technology through its post-marketing surveillance program. Sufficient national experience data should be available a year later to enable the NCHCT to proceed with a full, multifaceted assessment of MSAFP. Further, the CDC is planning to mount in FY 1981, in collaboration with the NCHCT and other PHS agencies, a controlled epidemiologic field study through which needed clinical data on MSAFP testing and screening for neural tube defects will be collected.

The NCHCT has initiated its extramural research program and funded

several research projects. A program announcement soliciting grant applications has been published. This solicitation is intended to stimulate research in two principal areas: (1) the development and testing of methodologies for assessing health care technologies, and (2) focused assessments or analyses of particular aspects of a health care technology, such as its social implications. These areas do not exhaust the research and related interests of the Center. Innovative and feasible proposals on other topics will also receive consideration for funding.

In addition to performing and sponsoring assessments, research, demonstrations, and evaluations in health care technology, the NCHCT is also responsible for disseminating the results of such efforts through a variety of channels. The Center will utilize OMAR/NIH paths, but will also disseminate evaluative information systematically to a wide range of providers of health services so that the knowledge regarding emerging, new, and existing medical technologies is made available as expeditiously and effectively as possible.

As assessments are completed and findings and recommendations are disseminated, the Council may develop exemplary criteria, standards, and norms regarding the appropriate use of specific technologies. Such criteria will be disseminated directly through the Center and through the National Library of Medicine to the Nation's hospitals, PSROs, Medicare fiscal intermediaries and carriers, other third-party payors, State and local HSA's, and other appropriate parties.

Existing Arrangements

Pertinent to the research initiative, representatives of departmental and other Federal agencies that are involved with the development, transfer, and assessment of health care technologies have been brought together in the TCC. Representatives of other Executive Branch organizations, as well as various HHS agencies and national advisory groups, are ex officio members of the Council. Intensive coordinating contacts therefore exist at the staff and policy levels among the Center and other Federal agencies with an interest in health care technologies. Liaison with the OTA and OSTP is frequent since both offices are represented on the TCC and the Council.

In accomplishing its mission, the NCHCT relies heavily on expertise within the PHS. The National Center for Health Statistics and the National Center for Health Services Research--both of the OHRST--as well as members of the immediate staff of that office--provide the NCHCT with statistical data and expertise, assistance in performing economic studies, grants and contract review, etc. The NCHCT is responsible for providing, for the PHS, scientific and medical advice to HCFA regarding the appropriateness of Medicare coverage for particular health care technologies. In this activity, NIH provides extensive medical and scientific advice to the Center, and the expertise of other PHS agencies, such as the FDA and CDC, is also frequently tapped by the NCHCT.

Proposed Scope of Activities

Clearly, fiscal realities and changes in assessment priorities will serve to determine the scope of the Center's research agenda at a given time. The NCHCT will continue, however, to undertake and sponsor activities in areas where assessments, research, demonstrations, and evaluations will be most responsive to national needs and priorities. Whenever possible, the Center will complement or cosponsor assessments of particular health care technologies that are being carried out by other Federal agencies. For example, joint activities are already under way with NIH, FDA, and ADAMHA, regarding the assessment of several technologies: the MSAFP test, PAP smear test, CT scanners, endoscopy in upper GI hemorrhage, and certain psychotherapeutic techniques.

The NCHCT is initiating both intramural and extramural research in those specific areas recommended by the Council, such as the utilization of diagnostic and therapeutic technologies in various settings; studies of the processes by which newly introduced technologies replace older ones; the criteria that determine the success or failure of medical technologies; and research on the critical ethical issues surrounding new or emerging technologies, especially matters of distributive justice. The Center's intramural staff have initiated preliminary analyses of the cost-effectiveness of several technologies.

The Center is cognizant of the need for a balanced assessment program --i.e., one that would include assessments of both medical devices and procedures and of "softer" technologies, such as the hospice concept. In undertaking such assessments, the Center would work closely with the agency or agencies having major responsibility in the particular area.

The NCHCT plans to continue to award new competing grants to enable extramural investigators to conduct assessments and research in health care technology. The Center also has authority to award grants and contracts to plan, establish, and operate extramural research centers. In anticipation of the need to broaden the Center's research capability, consideration is being given to awarding, in the future, a planning grant to an established academic or research institution. The Center will review with the NCHSR, NIH, and other agencies of the Department, as applicable, their experience in supporting extramural centers, and will also seek the advice of the Council and TCC. Depending on the findings and outcome of the planning phase, and the availability of resources, the Center will fund one extramural Center program.

For the research initiative, it is anticipated that the NCHCT's technology assessment program will expand during the next few years. As the Center's efforts fulfill various agency and departmental needs for the products of technology assessments, more agencies will be drawn to the activities of the NCHCT and TCC. Furthermore, organizations with health planning and standard-setting responsibilities, such as the National Council on Health Planning and Development, the National Professional Standards Review Council, and regulatory agencies such as HCFA and FDA will need to rely on the products of Center-sponsored assessments.

The results of technology assessments performed under this initiative

will be disseminated widely to researchers, health planners, practicing physicians and other health professionals, Federal agencies, third-party payors, industry, the Congress, and the public. To this end, the Center and collaborating agencies will seek the most effective forms of knowledge diffusion, and dissemination strategies will be modified accordingly to provide the best possible guidance to target groups.

Resources

The NCHCT estimates that the cost of an assessment of a health care technology, including dissemination of findings and recommendations, could range from $15,000 to $2,000,000. The cost of an assessment correlates with the scope and depth of the assessment undertaken and the need for additional research and special analyses. For example, if it is determined to limit the assessment to an evaluation of the economic, social, or ethical impact of a particular technology, an assessment could cost $15,000 to $50,000. On the other hand, if additional research is necessary to obtain needed data, a full assessment could cost several million dollars. Other costs associated with full assessments include the cost of conferences ($75,000 to $300,000) and overview papers ($1,500 each).

Table 8. RESOURCES FOR FY 1980-1981
(Dollars in Thousands)

	FY 1980	FY 1981 Budget
OHRST/NCHCT*	$ 1,990	$ 3,427

It is anticipated that portions of technology assessment costs will be distributed among agency cosponsors, as appropriate to mission and agreed upon in advance. Such distributions, however, can only be projected in terms of specific assessment projects.

*The figures indicated are for the NCHCT's technology assessment/research effort, and do not include program operations or administrative costs.

Chapter 16

NUTRITION RESEARCH

Sponsoring agency:

National Institutes of Health
Office of the Director

Cosponsors:

National Institutes of Health
All Institutes and the Division of Research Resources

Alcohol, Drug Abuse, and Mental Health Administration

Food and Drug Administration

Center for Disease Control

Office of Health Research, Statistics, and Technology
National Center for Health Statistics

Initiative coordinator:

Dr. Artemis P. Simopoulos
Chairman, NIH Nutrition Coordinating Committee
National Institutes of Health
Building 31, Room 4B59
9000 Rockville Pike
Bethesda, Maryland 20205
(301) 496-9281

Chapter 16

NUTRITION RESEARCH

Purpose and Rationale

The purpose of the nutrition research initiative is to develop within the Department of Health and Human Services a more comprehensive and effective program of nutrition research and training to strengthen support for related missions. To carry out this initiative, it will be necessary to structure a committee on the biomedical and behavioral aspects of nutrition research and training that will include all the agencies within the Department that either carry out or sponsor nutrition research and training. Departmental research so coordinated will in turn relate to broader Federal coordination efforts.

Within HHS, aspects of nutrition research, training, and its applications are supported by all 11 Institutes and 1 Division of NIH and by 5 other agencies of the Public Health Service. Their activities include:

- Support for basic and applied biomedical and behavioral research on the role of nutrients (carbohydrates, fats, proteins, vitamins, minerals, and water) and some nonnutrients, such as fiber, in human growth and development, health maintenance and promotion, and disease prevention

- Research in support of regulatory activity, including studies of human requirements for nutrients, their potential toxicity, and their interactions with one another and with toxic substances;

- Epidemiologic studies of diet and surveillance of nutritional status in selected populations, and the development and standardization of clinical tests and measurements appropriate to such studies;

- Assessment of nutritional status of the U.S. population;

- Nutrition research training and manpower development; and

- Nutrition curriculum development in medical schools, and nutrition education for health care providers and the public.

The appropriateness of an HHS initiative in nutrition research is suggested by rapidly growing scientific interest, lively public debate on the pertinence of nutrition to particular health problems, and evolving Federal efforts to coordinate nutrition research at both policy and program levels.

The interest of scientists has tended to focus on the precise role of nutrition in the promotion of health and the prevention and treatment of disease. As shown by a number of polls and surveys, the public also maintains a high interest in nutrition, especially its role in health maintenance and disease prevention.

Nature of the Health Problem

Nutritional science has seen the elimination of the ravages of many diseases caused by specific dietary deficiencies. It is now becoming apparent, however, that nutritional diseases are still among the most important health problems in the United States; and many diseases, such as atherosclerosis, hypertension, dental caries, obesity, alcoholism, and some forms of cancer, have nutritional components.

An important form of malnutrition in the United States is obesity. It is a primary risk factor for hypertension, increasing the morbidity and mortality from that disease, and is associated with diabetes. In addition, it imposes obvious social disadvantages on those afflicted. About 30 percent of men and 40 percent of women between the ages of 40 and 49 are overweight. A significant portion of these are technically "obese"--in excess of 20 percent above optimum weight. Obese children are three times more likely to be obese adults than children who are not overweight. Obesity is disproportionately common among persons in the least privileged socioeconomic groups.

Poor nutrition, in terms of undernutrition, detracts from the health of pregnant women, particularly adolescents, and leads to poor fetal development and to babies of low birth weight. Malnutrition of hospitalized patients leads to prolonged stays in hospitals and thus increased medical care costs. On the other hand, proper nutrition may improve the health status of the elderly.

Relationship to the Health Research Initiatives

The nutrition initiative relates to all five health research principles:

- Development of the relevant science base would maintain, encourage, and coordinate support for fundamental research in all aspects of human nutrition and its effects.

- In terms of clinical applications, the initiative would support and coordinate clinical research in nutrition and develop curricula aimed at imparting this knowledge to present and future health care providers.

- Through support of research on the safety of foods, food additives, and dietary supplements, the knowledge base is provided for regulatory action to ensure the safety of the Nation's food supply. Through epidemiologic surveys and surveillance, nutritional deficits and other nutritional problems are detected in target populations. Correlations are established among diet, nutritional status, and health, through

surveys such as the key Health and Nutrition Examination Survey (HANES).

- As for provision for research resources, the initiative would coordinate support for nutrition research training and manpower development and encourage interdisciplinary approaches to the solution of nutrition research problems.

- Finally, in terms of the fifth or unifying principle, the initiative would encourage broadly based inputs into program decisions through workshops, national and international conferences, and interaction with certain groups. These include the Office of International Health/ Office of the Secretary, HHS; the Joint Subcommittee on Human Nutrition Research/Office of Science and Technology Policy (JSHNR/OSTP); the HHS and NIH Nutrition Coordination Committees; and the ongoing peer review processes of the PHS.

Implementing Arrangements

Current Scope of Research Activity

The following HHS agencies support programs in nutrition research:

National Institutes of Health. NIH, under its very broad research mandate provides the main Federal support for biomedical and behavioral nutrition research and research training. All 11 Institutes and the Division of Research Resources support aspects of this research, which include the role of nutrients on human growth and development, health maintenance and promotion, disease prevention, and disease treatment; the role of nutrition during pregnancy, infancy, and old age; research on nutrient toxicity, bioavailability, and interaction, as well as on food composition and dietary and nutritional status; and nutrition education research as a component of some of the intervention trials.

Alcohol, Drug Abuse, and Mental Health Administration. The ADAMHA nutrition research program, primarily housed in the National Institute of Mental Health, focuses on biological, behavioral, and psychological factors in the development of obesity and anorexia nervosa; cognitive, emotional, motivational, and other psychosocial factors that may be predictive of these nutrition-related behaviors; assessment of the impact of psychotherapeutic drugs on the nutritional status of psychiatric patients; the relationship of nutrition to normal and abnormal brain development; the effects of alcohol on fetal development; and the interaction of alcohol with nutrients and drugs.

Food and Drug Administration. The nutrition research program of the Bureau of Foods, FDA, is directed toward studies that will provide data for regulating the nutritional quality and safety of the food supply, the practice of sound nutrition principles for the dietary management of disease or special physiologic states, and the establishment of food-labeling criteria to protect the consumer from misleading information or fraud. This research program comprises both experimental and clinical nutrition research in nutrient toxicity, nutrient interactions, and nutrient bioavailability. In addition, the FDA conducts research on the development of methodology for the determination of nutrients and other substances found in food and for the measurement of food

consumption and consumer behavior relative to food purchasing.

Center for Disease Control. The CDC carries out surveillance in specific population groups and thus generates new knowledge needed for the direction of further research efforts in nutrition. In addition, CDC's clinical laboratory monitors quality control and develops methods applicable in the field for surveys, including HANES.

National Center for Health Statistics. Through its HANES program, the NCHS, in the Office of Health Research, Statistics, and Technology (OHRST), surveys and monitors nutritional status in a national probability sample of the U.S. population, and relates these data to a variety of simultaneously determined health parameters, thus broadening our knowledge of nutritional status of the population.

Existing Arrangements

NIH, recognizing the need for a coordinated approach in this multidisciplinary field, established the NIH Nutrition Coordinating Committee (NIH-NCC) in 1975, with members from each of the Institutes and Divisions that support nutrition research. The purpose of the Committee is fourfold: to review and comment on the plans, execution, and results of research efforts in order to develop the Program in Biomedical and Behavioral Nutrition Research and Training; to process and respond to incoming requests for nutrition information from HHS and other Federal agencies, the higher Executive Branch, the Congress, scientific institutions, and the public; to maintain up-to-date information on NIH funding and nutrition research activities; and to develop and monitor the means for improving the coordination of these activities.

Over the past two years, the NIH-NCC has expanded to include liaison members from additional NIH components that have an interest in nutrition, such as the National Library of Medicine, and from other agencies of PHS, notably the National Institute of Mental Health and the National Institute of Alcohol Abuse and Alcoholism of ADAMHA; FDA; the Bureau of Health Manpower of HRA; CDC; and the National Center for Health Statistics of OHRST. These liaison members regularly attend the monthly NIH-NCC meetings and participate in Committee activities.

At the level of the PHS, the Chairman of the NIH-NCC is also the Chairman of the Subcommittee of Nutrition Research of the DHHS-NCC and a member of both the DHHS-NCC and the DHHS-Nutrition Policy Board.

Above the PHS and HHS levels, interdepartmental coordination in nutrition research is achieved through the Joint Subcommittee on Human Nutrition Research (JSHNR) of OSTP, which the chairman of the NIH-NCC cochairs. This subcommittee includes representatives from the Agency for International Development, Department of Agriculture, Department of Defense, Department of Health and Human Services, Federal Trade Commission, National Science Foundation, Veterans Administration, National Aeronautics and Space Administration, and OSTP.

The JSHNR is concerned with all federally supported or conducted research on human nutrition and professional personnel needs in human nutrition research

and education. The purpose of the JSHNR is to increase the overall effectiveness and productivity of Federal research efforts in human nutrition.

The NIH-NCC has facilitated the development of a comprehensive trans-NIH program in the biomedical and behavioral aspects of nutrition research and training. This program consists of the following major components: nutrition and disease prevention, nutrition and genetics, behavioral studies in nutrition, international studies in nutrition, nutrition and epidemiology, obesity, nutritional status, maternal nutrition, child and infant nutrition, nutrition and aging, total parenteral nutrition, nutrition education research, and nutrition education for the public and for professionals.

Significant accomplishments of the NIH-NCC include:

- A major new development of joint efforts in nutrition research among NIH, ADAMHA, FDA, and CDC is the establishment of the five-year study of infants who developed hypochloremic metabolic alkalosis following feedings of a chloride-deficient formula. The study, established at the request of the NCC office, is carried out by intramural scientists of the NIH and ADAMHA, with FDA and CDC scientists as advisers.

- The development of a program announcement on overnutrition and obesity, with participation from several Institutes--NIAMDD, NHLBI, NIA, NIAID, NICHD, and NINCDS--and inclusion of the research needs of the FDA.

- A concerted attempt to attract additional scientists, through National Research Service Awards for institutions and individuals (postdoctoral fellowships), into areas of specific interest in nutrition research. Institutes participating in these announcements include the NCI, NEI, NHLBI, NIAID, NIA, NIAMDD, NIDR, NIEHS, and NINCDS. In expanding manpower development in nutrition, NIH and ADAMHA have developed a joint announcement for New Investigator Research Awards that includes NIA, NCI, NIAMDD, NICHD, NIDR, NIMH, and NIAAA.

- The publication of a Request for Applications for core grants to establish Clinical Nutrition Research Units, with the participation of three Institutes: NIA, NIAMDD, and NCI.

- Conference on Nutritional Status: Research and Surveys, cosponsored by NIH, FDA, CDC, and NCHS-HANES, and held at NIH on September 22-23, 1980.

- The establishment by the DHHS-NCC of a Subcommittee on Nutrition Research and Research Training, including research into nutrition education. The Subcommittee, chaired by the chairman of the NIH-NCC, draws its members from ADAMHA, FDA, CDC, and NCHS-HANES.

Proposed Scope of Research Activities

The principal thrust of the nutrition research initiative will be to reinforce the coherent research program that has been developed and to extend the growing trans-Institute cooperation in the area of nutrition research to other agencies. In this way an appropriate program can be mutually supported and strengthened. A global view of problems will also permit more rapid

identification of knowledge gaps, with cooperative action toward their solution.

For the further development of nutrition research and training activities under the initiative, it is anticipated that a key role will be played by the recently established NIH program of core grants for Clinical Nutrition Research Units (CNRUs). The creation of such core grant units is considered the most feasible way to integrate the research, education, and service activities that are oriented toward human nutrition in health and disease.

NIH funded seven such units in fiscal 1979 and '80 throughout the United States. Thus, a strengthened national program on the biomedical and behavioral aspects of clinical nutrition has been established, including fundamental research, clinical investigations, and population studies, and will provide the appropriate environment for the support of training and nutrition services. Under consideration is the issuance of another Request for Applications on CNRUs, with increased participation from other Institutes within NIH, FDA, ADAMHA, and other agencies. The FDA has signified its intent to join NIH in this program (through the mechanism of interagency reimbursement agreements) by supporting additional CNRUs, where the research will be geared to the study of nutrient toxicity and of nutrient-drug interactions throughout the life span, but with particular emphasis on infants and children. The HRA has expressed interest in joining the CNRU program in order to expand the nutrition training and education of physicians and other health professionals. Discussions with ADAMHA may lead to its support of additional CNRUs whose research will focus on the behavioral and psychological aspects of extremes in nutrition, such as anorexia nervosa and obesity, and the relationship of nutrients to neurotransmitters. Another unit is envisioned as becoming the focus for studies on interrelationships of alcohol and nutrition and on the interaction of drugs and nutrients to influence drug abuse.

In addition, intramural coordination, principally between NIH and NIMH/ADAMHA, will occur through the establishment of an intramural CNRU.

It is expected that data developed by such a national program in clinical nutrition research will be used by other agencies, such as NCHS and CDC, for nutrition surveillance and for a nutritional-status monitoring system.

The specific objectives of the CNRU program are--

- To create or strengthen foci in biomedical research institutions for multidisciplinary research in clinical nutrition, in order to develop new knowledge about specific nutrients in health, human development, and the prevention and treatment of disease;

- To strengthen training environments in order to improve the education of medical students, house staff, practicing physicians, and paramedical personnel in clinical nutrition; and

- To enhance patient care and promote good health by focusing attention on clinical nutrition and generating nutritional information for the public.

New Arrangements

To carry out the nutrition initiative and develop a cohesive program for the Department, it will be necessary to stucture a committee with members (one or more as appropriate) from the six agencies that conduct or support nutrition research and training: NIH, FDA, ADAMHA, CDC, and OHRST/NCHS. This Committee on the Biomedical and Behavioral Aspects of Nutrition Research and Training will have the following responsibilities:

- Review and comment on the plans, execution, and results of research efforts, in order to refine and strengthen the Department's nutrition program;
- Coordinate research stemming from the obesity program, the CNRUs, nutrition research training and manpower development programs, and participation in OSTP's JSHNR;
- Provide information and advice on the nutrition research program to the directors of the agencies involved, to the Office of the Assistant Secretary for Health, and to the Office of the Secretary;
- Continuously evaluate research data and provide advice for the development of nutrition education materials for the public; and
- Plan and arrange for conferences, workshops, consensus development exercises, and reports as appropriate.

Table 9. RESOURCES FOR FY 1980-1981
(Dollars in Thousands)

	FY 1980	FY 1981 Budget
ADAMHA	$ 4,954	$ 5,429
FDA	4,389	4,690
CDC	220	240
OHRST/NCHS*	---	---
NIH	146,384	153,683

*The NCHS, a general-purpose statistical agency, will be actively involved in this initiative through conduct of the HANES study and support of other agencies' efforts by interagency agreements.

Chapter 17

PREVENTION OF OCCUPATIONAL DISEASE THROUGH CONTROL TECHNOLOGY TO REDUCE EXPOSURE TO TOXIC CHEMICALS

Sponsoring agency:

Center for Disease Control
National Institute for Occupational Safety and Health

Proposed participating agencies:

National Institutes of Health
National Cancer Institute

Office of Health Research, Statistics, and Technology
National Center for Health Statistics

Initiative coordinator:

Dr. Kenneth Bridbord
Director
Office of Extramural
Coordination and Special Projects
National Institute for Occupational
Safety and Health, CDC
Parklawn Building, Room 8-47
5600 Fishers Lane
Rockville, Maryland 20857
(301) 443-6437

Chapter 17

PREVENTION OF OCCUPATIONAL DISEASE THROUGH CONTROL TECHNOLOGY TO REDUCE EXPOSURE TO TOXIC CHEMICALS

Purpose and Rationale

The purpose of this initiative is to develop within the Department an effective program of research in control technology to prevent exposure of American workers to hazardous chemicals in the workplace and thus prevent needless disease. The need for a Departmental initiative in control technology is suggested by a number of recent reports and recommendations:

- The Surgeon General's Report on Health Promotion and Disease Prevention recognizes the leadership role of the Department in preventive medicine, including the prevention of work-related disease.

- The Health Services Research, Health Statistics, and Health Care Technology Act of 1978 (P.L. 95-623) requires that the Secretary, in coordination with the National Academy of Sciences, ascertain the extent to which chemicals are contributing to disease, determine the health effects of reducing environmental exposure to toxic agents, and prepare periodic reports to the Congress.

- The Biomedical Research, Community Mental Health Centers, and Protection of Human Subjects Act (P.L. 95-622) requires that the Secretary prepare an annual report on carcinogens that includes a list of all known carcinogens, information on the nature of exposure and the number of persons exposed, and an evaluation of relevant regulatory standards. The information requirements for this annual report again suggest the need for a research initiative in control technology.

- The report to the President from the Toxic Substance Strategy Committee recommends that additional emphasis be placed on control technology research to prevent occupationally related disease.

- Departmental estimates that 20 percent or more of cancers are related in part to occupational exposure to toxic chemicals again point to the need for control technology research.

Within HHS, the National Institute for Occupational Safety and Health (NIOSH) was given the lead under the Occupational Safety and Health Act of 1970 for "providing research, information, education and training in the field of occupational safety and health." Currently NIOSH is the only HHS

organizational component with a mandate to solve work-related problems through control technology. However, a large number of other HHS research programs provide information that is necessary to support a Departmental initiative in development of technology for control of toxic chemicals. Among the supporting Departmental research programs that identify toxic exposures pointing to the need for control technology research are--

- The National Toxicology Program, including portions of toxicology research programs from NCI and NIOSH;
- Epidemiology research conducted by NIOSH and NCI; and
- The research programs related to reproduction which are included in the proposed initiative on "Prevention of Reproductive Effects Due to Workplace Hazards" (Chapter 18).

It is envisioned that NIOSH will continue to be the principal Departmental organization conducting research on control technology, with information on toxic-chemical hazards based on recent toxicologic and epidemiologic research from other programs helping to focus the research effort on high-priority and newly identified problems.

Nature and Magnitude of the Health Problem

Control technology is a concept of hazard prevention which functions at the source--the general work environment and the worker--to decrease human exposure there and in the general environment. The elements that are essential to achieve workplace control as the first line of defense are engineering control measures, control monitoring, work practices, and personal protective equipment. An excellent example of how control technology can be applied is the action that was taken upon the recognition of vinyl chloride as a human carcinogen, resulting in reductions of occupational exposures from hundreds of parts per million to less than 1 ppm.

The need for control technology research is clearly apparent from the number of workers who are engaged in the production of tens of thousands of chemicals and who suffer as a result of workplace exposure. Occupational exposures to chemicals are estimated to be contributing factors in as many as 100,000 deaths each year. The reduction of exposure through control technology will have a major impact on the incidence and prevalence of occupational disease.

Relationship to the Health Research Principles

The initiative stems from the third Health Research Principle, which expresses the need to generate the "basic information that underlies government regulation related to public health." Lack of available technology to control toxic chemicals has been one of the major obstacles to effective Federal regulations to protect workers and the general public.

The initiative also relates to the second Health Research Principle through its intent to support applied problem-oriented research with the aim of preventing disease. In addition, the initiative relates to the fourth Health Research Principle through its effort to sustain research capabilities of individuals and institutions in the field of disease prevention. The emphasis on disease prevention should be a valuable complement to other initiatives that seek to quantify adverse environmental effects.

Implementing Arrangements

Current Scope of Research Activity

The following HHS agencies actively support programs in control technology research, or support studies which directly apply to decision-making in the Control Technology Program.

National Institute for Occupational Safety and Health. In 1976 NIOSH (CDC) established a pioneer effort referred to as the Control Technology Program (CTP) to emphasize solutions for problems of hazardous chemical exposures in the workplace. The initial work activities have focused on the following topics:

- Control technology assessment of major industries and industrial processes, including identification of research gaps;
- Engineering control research for specific control methods;
- Control monitoring research for specific monitoring systems;
- Protective equipment research;
- Work practice and incentives research; and
- Short- and long-term training.

The above activities are conducted by in-house professional staff, research contractors, and the recipients of research and training grants. A recent accomplishment was the completion of a control technology assessment in the plastics industry which demonstrated how controls developed for vinyl chloride were applicable to acrylonitrile, another carcinogen. This analysis contributed to a recent OSHA standard for acrylonitrile.

NIOSH has been collaborating with NIEHS, the Environmental Protection Agency, and the Department of Energy in an interagency program to assess the health implications of developing energy technologies and to develop appropriate control measures to protect workers and the general population.

National Cancer Institute. The NCI has been contributing to the NIOSH program in control technology through an interagency agreement aimed at the identification of chemicals in the workplace associated with increased cancer risk and at prevention of exposure to such agents.

Related Research Activity

The following HHS agencies and programs do not conduct control technology research as such, but are engaged in programs that produce relevant information.

CDC/NIOSH. NIOSH industry-wide studies and health hazard evaluations frequently identify hazardous chemicals and industrial processes that would be suitable subjects for control technology research. The second National Occupational Hazard Survey will also contribute to the control technology initiative by identifying groups of workers exposed to hazardous substances.

National Toxicology Program. The goal of the NTP is to strengthen the Department's activities in the testing of chemicals of public health concern. New toxicologic information from the NTP will pinpoint appropriate areas for additional control technology research.

National Center for Health Statistics. P.L. 95-623 expands the role of the NCHS in the area of occupational and environmental health, which relates directly to the control technology initiative.

In addition to the contributing agencies and programs listed above, the Occupational Safety and Health Administration/Department of Labor, the Mine Safety and Health Administration/Department of Labor, the Bureau of Mines/Department of the Interior, and the Environmental Protection Agency are potential contributors to the control technology research initiative.

Existing Arrangements

Coordination of control technology research within and outside HHS has been on both a formal and informal basis. The need to emphasize control technology research has been brought to the attention of the Assistant Secretary for Health and proposed to the National Advisory Committee on Occupational Safety and Health (NACOSH). The Toxic Substances Strategy Committee, coordinated by the Council on Environmental Quality, conducted a review of Federal toxic-related research, including control technology, which recognized the need for an expanded control technology program in occupational health. A recently completed review of Federal toxic-related research by the Office of Management and Budget also identified the relatively low level of activity in this field.

The Department is considering other research related to control technology as a result of a followup to identify the minimum essential uses for asbestos and to encourage the use of safe asbestos substitutes. NIOSH and NCI have also been collaborating on a joint research grant program to assess the effectiveness of existing control technology to protect workers involved in the renovation of school buildings containing asbestos.

The Mine Health Research Advisory Committee is a council to NIOSH in the area of mine-related research. The NHLBI, the Bureau of Mines, and the Mine Safety and Health Administration are also members of this committee, which frequently acts as a focus to coordinate research on control technology.

NIOSH and EPA have also been collaborating in the development of control technology to protect workers and the general population. In addition, NIOSH has been collaborating with the NCHS and NCI to develop Departmental responses to P.L. 95-622 and 95-623, respectively.

During the past two years, NIOSH has established control technology to prevent exposure to toxic chemicals as a special emphasis area under its research grants program.

Proposed Scope of Research Activity

This proposed initiative to develop control technology will strengthen the effort of the Department in disease prevention by assuring that a wide range of HHS research efforts to identify hazardous substances are translated into actual disease prevention activities. The proposed scope is based on the establishment of seven specific research program areas:

Control Technology Assessment. The assessment work will document exemplary practices in control technology which can be applied in the near term to protect workers.

Engineering Control Technology Research and Development. This program area will focus on the filling of research gaps identified in the assessment activity, including new process equipment and the building of less hazardous plants.

Control Monitoring Research and Development. This program will concentrate on the evaluation and development of area and on-line monitoring systems to measure worker exposure to toxic chemicals, including systems based on miniaturized and real-time monitoring equipment.

Technology Transfer. Included in this program area will be major efforts to conduct field demonstrations, disseminate technical information, and recommend guidelines and standards for control technology. The results from this research will be widely disseminated to those groups that have interest in or may be affected by these findings, including industry, labor, workers, other government agencies, the academic community, and public interest groups. Possible e ethical issues associated with these findings will be evaluated, such as effects on insurance rates.

Training. Continuing education for professional personnel will be accomplished by short-term training. Long-term training will be required to attract and educate personnel in control technology, with emphasis on the education of engineers.

Work Practices and Incentives Research. This research activity will identify means to influence management and labor to reduce occupational exposure.

Protective Equipment Research and Testing. This activity will result in development of improved personal-protection equipment to help prevent exposure of workers to hazardous chemicals.

New Arrangements

To carry out the control technology initiative and develop a cohesive program for the Department, it will be necessary to structure a committee including representatives from the organizations that directly support or conduct related research and training: NIOSH, NCI, and NCHS. In addition to HHS agencies, membership on this committee will include the Occupational Safety and Health Administration, Mine Safety and Health Administration, Bureau of Mines, and Environmental Protection Agency. In view of the major NIOSH activty in control technology, it is proposed that NIOSH not only chair this committee, but also provide the necessary staff support.

Responsibilities of the Committee on Control Technology Research will be to review and comment on the plans, execution, and results of research effort; to coordinate research training; to advise the Directors of the agencies involved, the Office of the Assistant Secretary for Health, and the Office of the Secretary on matters related to control technology, including the setting of priorities; to evaluate research data and provide advice for the development of professional and lay educational materials; and to plan and arrange for conferences, workshops, consensus-development exercises, and reports as appropriate.

Table 10. RESOURCES FOR FY 1980-1981
(Dollars in Thousands)

	FY 1980	FY 1981 Budget
CDC/NIOSH	$ 4,416	$ 4,416
NIH/NCI*	18,980	18,501
OHRST/NCHS**	---	---

*NCI's contribution is exclusive of commitments to NTP.

**The NCHS, a general purpose statistical agency, will be actively involved in the initiative through support of other agencies' efforts by interagency agreements.

Chapter 18

PREVENTION OF REPRODUCTIVE EFFECTS DUE TO WORKPLACE HAZARDS

Sponsoring agency:

Center for Disease Control
National Institute for Occupational Safety and Health

Cosponsors:

National Institutes of Health
National Institute of Environmental Health Sciences
National Institute of Child Health and Human Development

Food and Drug Administration

Center for Disease Control
Bureau of Epidemiology

Office of Health Research, Statistics, and Technology
National Center for Health Statistics

Social Security Administration

Initiative coordinator:

Dr. Kenneth Bridbord
Director, Office of Extramural
Coordination and Special Projects
National Institute for Occupational Safety and Health
Parklawn Building, Room 8-47
5600 Fishers Lane
Rockville, Maryland 20857
(301) 443-6437

Chapter 18

PREVENTION OF REPRODUCTIVE EFFECTS DUE TO WORKPLACE HAZARDS

Purpose and Rationale

This initiative will establish an integrated program of cooperation and coordination among those HHS agencies performing research on reproductive hazards, in order to greatly improve efforts to identify and quantify occurrences of such hazards in the workplace. These efforts can be expected to result in a more healthful work environment for the American employee. This initiative is complementary to and will be closely coordinated with the proposed initiative "Prevention of Birth Defects," sponsored by the National Institute of Child Health and Human Development.

A 1975 Report to the Secretary prepared by Vilma Hunt, dealing with occupational health problems of pregnant women, recommended that the Department expand its effort in the area of reproductive effects research. A 1976 "Report of a Work-Group on Occupational Mutagenesis, Teratogenesis, and Transplacental Carcinogenesis," developed by a committee with representatives from CDC (NIOSH and the Bureau of Epidemiology), NIH (NIEHS and NICHD), FDA, and the Health Services Administration, recognized the potential reproductive hazards posed by paternal as well as maternal exposure to toxic substances and pointed to the need for an expanded HHS effort in this regard. NIOSH, in 1976, sponsored a Conference on Women and the Workplace which highlighted results of current studies and emphasized the need for additional research.

In 1977 NIOSH published a research report entitled "Guidelines on Pregnancy and Work," prepared under contract with the American College of Obstetricians and Gynecologists. This report again emphasized the importance of reproductive effects associated with the workplace. NIOSH supported a conference in 1978 to evaluate current methodologies for assessment of occupationally related reproductive hazards. The recent "Surgeon General's Report on Health Promotion and Disease Prevention" establishes clear goals to reduce the number of low-birth-weight infants and the number of birth defects. Recent legislation (P.L. 95-623) also requires the Department to identify environmental factors contributing to birth defects and genetic damage.

The issue of reproductive effects and the workplace is also of special concern to the Equal Employment Opportunity Commission, which is currently developing policies to deal with alleged sex discrimination due to refusal of companies to hire women into certain potentially hazardous occupations without adequately recognizing similar hazards to men. Research is required to identify hazards that may produce adverse effects through both maternal and paternal exposures.

To carry out this initiative, a Committee on Reproductive Hazards in the Workplace is proposed. This should include representatives from NIOSH, CDC's Bureau of Epidemiology, NIEHS, NICHD, FDA, NCHS, and SSA. It is envisioned that NIOSH would chair this committee, based upon its lead responsibility within HHS in occupational safety and health as outlined in the 1970 Occupational Safety and Health Act. The committee would act as a coordinating body to assure that the Department effectively addresses the problem of reproductive hazards in the workplace.

Nature and Magnitude of the Health Problem

The social, economic, and personal burdens of sterility, spontaneous abortion, and mental, physical, and biochemical congenital defects are well recognized. The March of Dimes estimates that approximately 15 million Americans are affected by some form of birth defect, including mental retardation, structural malformations, and errors in metabolism.

Little attention has been given to the harmful reproductive effects that could be caused by occupational exposure of pregnant women and potential fathers to hazardous industrial materials. More than 1,000 new chemical compounds are developed each year and added to the tens of thousands of chemicals and 2 million mixtures, formulations, and blends already in commercial use. The possibility that congenital malformations or childhood cancer may be related to prenatal environmental or occupational exposures implies an urgent need to correlate laboratory studies of mutation with reproductive studies of exposed population groups.

Goals and Objectives of the Initiative

HHS objectives include identification of reproductive hazards in the workplace and prevention of injury or chemical intoxication of workers and their offspring. Goals to reach these objectives include--

- Defining the biochemistry of mutagenesis and teratogenesis;
- Defining the expected incidence of various reproductive outcomes in the general population and in special ethnic, racial, geographic, age-specific, and socioeconomic subpopulations;
- Screening large numbers of chemicals for mutagenic, teratogenic, transplacental carcinogenic, and fertility-inhibiting actions;
- Identifying groups of workers with abnormal reproductive experience and determining the probable cause; and
- Identifying workers exposed to potential reproductive hazards and controlling the hazards.

The magnitude of this problem demands an approach that moves expeditiously from potentially relevant areas of basic research to practical application. Individual HHS projects have provided significant elements of the foundation necessary for effecting public health intervention. This document outlines one way to organize an HHS "Initiative on Prevention of Reproductive Effects Due to Workplace Hazards."

Relationship to the Health Research Principles

This initiative relates to the first Health Research Principle through its emphasis upon fundamental research efforts to discover the toxic effects of various chemical and physical agents upon reproductive processes. It also relates to the third Principle by stressing the use of findings from fundamental studies for regulatory decisions and preventive and control measures.

Implementing Arrangements

The strategy for a program of reproductive studies requires two interrelated approaches:

- Epidemiologic investigations into reproductive failure and parental exposure. Reproductive failure can be studied through a monitoring or warning method employing existing vital statistics and hospital or birth-defects registries as primary data sources. Parental exposure studies can be initiated if either surveillance data or animal experiments indicate that any geographic area, occupational group, or industrial agency is suspect or significant.

- Laboratory experiments to screen agents for potentially harmful effects and to confirm agents as hazardous that are suspected through epidemiologic investigation.

This entire initiative must be developed into an integrated program with sufficient coordination, cooperation, and communication among participating agencies and institutions to preclude needless duplication of effort and to facilitate oversight of pertinent developments in the many parts of HHS. The organizational machinery available to support these approaches includes in-house studies, contracts, grants, and cooperative agreements with other agencies and institutions. In addition, current-awareness literature searches will be a key support element for the entire endeavor.

Existing Arrangements

Coordination of research on reproductive effects within and outside HHS has been on both a formal and informal basis. In 1976 NIOSH took the lead in calling on Departmental experts to develop a "Report on Occupational Mutagenesis, Teratogenesis and Transplacental Carcinogenesis." The Committee to Coordinate Environmental and Related Programs has had a long-standing subcommittee dealing with environmental mutagenesis. NIOSH has briefed the National

Advisory Committee on Occupational Safety and Health on the problem of reproductive efforts. Recent legislation (P.L. 96-623) requires the Department to identify environmental factors contributing to birth defects and genetic damage, with lead coordinating responsibility in the NCHS. NIOSH has also established reproductive effects as a special-emphasis area under its research grants program.

Current and Proposed Research Efforts

Combatting reproductive hazards is a goal shared by a number of agencies within HHS. Each of the agencies listed below was invited to submit comments concerning its efforts pertinent to this study.

National Institute for Occupational Safety and Health. NIOSH has several ongoing and proposed projects in the areas of epidemiologic investigations and laboratory toxicology studies:

- Epidemiologic Investigations. The Reproductive Failure Approach includes five ongoing projects investigating rare inherited diseases and natality outcomes; relationships between occupation and the various outcomes of pregnancy; spontaneous abortions among employed women; the association between parental occupation and childhood cancer cases; and a fetal mortality study assessing parental employment as related to selected causes of fetal death.

  New projects within the Reproductive Failure Approach will assess the applicability of infertility clinic records; assess utility of the National Occupational Health Survey(s) in identifying target industry areas for study; and support and encourage investigators exploring associations between parental occupations and reproductive wastage.

  Among the new projects proposed are the development of questionnaires for personal or telephone interviews; semen analysis and associated male reproductive history; cytogenetic studies (mutations in somatic cells) and physical examination for testicular atrophy; studies using serum measurement of neurohormones and reproductive hormones; investigation into behavioral changes in the offspring of exposed workers; and investigations of the roles of trauma, stress, and physical agents in reproductive failure.

- Laboratory Toxicology Approach. In the NIOSH Laboratory Toxicology Program, chemicals are selected according to extent of occupational exposure, production and usage patterns, and known chemical or toxicological properties. Most chemicals tested are screened in more than one test system, including various *in vitro* mutagenesis assays.

  Grants support research in a number of related areas, including animal studies of arsenic and inhalation anesthetics, an epidemiologic survey of reproductive outcomes among dentists exposed to inhalation anesthetics, a study of potential correlations between occupational exposures and selected congenital defects, and an investigation of the effects of pesticide exposure on women.

National Institute of Environmental Health Sciences. The Institute is conducting research in developmental and reproductive toxicology, including broad-based studies on the effects and mechanism of toxicity from chemical agents. Approaches include studying molecular mechanisms of toxicity, studying the pharmacokinetics of chemicals in perinatal animals, developing model systems for man, developing better procedures for detection of early toxic effects and predictions of human toxicity, developing and validating an embryo culture system for predicting chemical teratogenesis, and identifying biochemical markers (such as enzymes) that can indicate toxicity during the perinatal and developmental periods.

A fertilization system using human sperm and hamster ova to test for altered fertility induced by environmental agents has been developed and is being validated.

Research in mutagenesis focuses on evaluating the molecular nature of mutation and repair processes in the various types of mutational events produced and isolated, and on characterizing mutant mammalian proteins and enzymes that may serve as markers for chemically induced mutations in laboratory test systems. Efforts continue toward determining the mechanisms of action of various known mutagens and refining and validating test systems using microbes and other lower organisms. These systems are suitable for rapid and inexpensive initial screening of chemicals for mutagenicity. Long-term studies will continue with mice and other mammals to develop screening systems capable of detecting mutations simultaneously over a large number of genes. Several studies continue on human somatic mutations and mouse germinal mutations, and on identification of biochemical and immunological indicators that can be used for monitoring mutation frequency in humans.

Food and Drug Administration. The FDA program consists essentially of mission-oriented applied research related to drugs, cosmetics, food additives, and food contaminants. The toxicology and testing research effort is small as compared with non-FDA-supported research, because the laws administered by FDA generally require manufacturers to submit data in support of the safety and efficacy of products under FDA's jurisdiction. The National Center for Toxicologic Research (NCTR) supports the FDA program through determination of basic biological processes that will permit better extrapolation of toxicologic data from laboratory animals to man and the development of improved methods and test protocols.

Research in mutagenesis and teratogenesis supported by the NCTR and various FDA Bureaus includes methods development and the validation of *in vitro* tests, development of hamsters as an animal model for teratogenesis testing, and development of strategies for neurobehavioral toxicity testing.

National Institute of Child Health and Human Development. The Institute conducts basic research on aspects of pregnancy outcome. Some of this research has direct bearing on the initiative by serving to elucidate the effect of workplace environments on the physiology of pregnant women, to discover elements in specific workplace environments that contribute to stress on fetal development, and to define relationships between the work of pregnant women and the initiation of labor.

Center for Disease Control. CDC is carrying out epidemiologic studies through both the reproductive failure and the parental exposure approaches. The reproductive approach has included ongoing studies using the Atlanta Birth Defects Registry and special studies working from established data bases. The Center gathers occupational histories related to the Atlanta data base and has published analyses of these data. CDC would like to establish three or four systems, somewhat similar to Atlanta's, in cities with different industrial or environmental characteristics. Within the parental exposure approach, CDC has done special community studies on the effects of various environmental exposures on reproductive outcome. An example is a study on the effects of airport noise in Atlanta. The CDC also responds to requests for epidemiologic assistance concerning reproductive hazards.

National Center for Health Statistics. This is the lead agency for the Fetal Mortality Study, described above, and is engaged in the major effort to plan for the collection and coordination of statistical and epidemiologic data on the effects of the environment on health.

Proposed Cooperative Arrangements

To carry out this initiative, a committee is proposed that will include representatives from the seven organizations directly supporting or collaborating in such research within the Department: NIOSH, CDC's Bureau of Epidemiology, NIEHS, NICHD, FDA, NCHS, and SSA. The Social Security Administration is included on the committee because it maintains a computerized file to complete work histories for 1 percent of covered workers. Procedures to permit using these data, while protecting privacy, need to be worked out, and staffing and funding arrangements must be developed so that the SSA does not bear the expense for research unless it is clearly cost-effective within that agency's own framework. The agency is actively engaged in trying to turn this data base to epidemiologic use. A project called Linked Administrative Statistical Samples (LASS) is undertaking mortality research in which the Complete Work History Sample figures prominently.

It is proposed that NIOSH chair such a committee. To make the results of HHS research more relevant to the needs of the regulatory agencies, it is proposed that liaison membership also be offered to interested organizations outside the Department: the Occupational Safety and Health Administration (OSHA), Mine Safety and Health Administration, Environmental Protection Agency, and Consumer Product Safety Commission. Responsibilities of the committee will be to review and comment on the plans, execution, and results of research efforts to assess reproductive hazards in the workplace; to coordinate research training in the area of reproductive toxicology and epidemiology; to provide advice to the Directors of the agencies involved, to the Office of the Assistant Secretary for Health, and to the Office of the Secretary on matters related to reproductive hazards in the workplace; to continuously evaluate research data and provide advice for the development of educational material for the general public; and to plan and arrange for conferences, workshops, consensus development exercises, and reports as appropriate. Specific projects where interagency cooperation might be useful include selection of cities and data elements for a new birth defects registry (CDC/NIOSH) and expansion of the telephone reproductive history capabilities to meet other needs (NICHD/NIOSH).

Translation of Research Findings to Programs of Prevention

While the emphasis within HHS calls for less control than research, control follows quickly. The technology for protecting workers is usually straightforward and available to larger companies. Smaller companies may need consultation, which can be obtained through OSHA, NIOSH, or the Small Business Administration. The key is identifying and publicizing hazards. Planning, however, should be started now for public and worker education, for improvement that may be required within the framework of present law, for new legislation that may be required to meet problems, and for publication and dissemination of the findings from research.

The results from this research will be widely disseminated to those groups that have interest in or may be affected by these findings, including industry, labor, workers, other government agencies, the academic community, and public interest groups. Possible ethical issues associated with these findings will be evaluated, such as job discrimination among high-risk populations and the effect of risk status on insurance rates.

Table 11. RESOURCES FOR FY 1980-1981
(Dollars in Thousands)

	FY 1980	FY 1981 budget
CDC/NIOSH	$ 2,849	$ 2,849
FDA*	3,088	3,224
OHRST/NCHS**	---	---
NIH total	5,000	5,000
NICHD	(-----)	(-----)
NIEHS	(5,000)	(5,000)

*Approximately 50 percent of the resources displaved for this initiative are also included in FDA resources directed to NTP.

**The NCHS, a general purpose statistical agency, will be actively involved in the initiative through support of other agencies' efforts through interagency agreements.

Chapter 19

THE ROLE OF THE INDIVIDUAL CONSUMER IN HEALTH PROMOTION AND HEALTH CARE

Sponsoring agency:

Health Services Administration
- Bureau of Medical Services
- Bureau of Community Health Services
- Indian Health Service

Cosponsors:

Center for Disease Control

Alcohol Drug Abuse, and Mental Health Administration

National Institutes of Health

Health Resources Administration

Office of the Assistant Secretary for Health
- Office of Health Information and Health Promotion
- Office of Health Research, Statistics, and Technology
  - National Center for Health Services Research

Health Care Financing Administration
- Office of Research, Demonstrations, and Statistics

Food and Drug Administration

Initiative Coordinator:

Mr. Ronald H. Carlson
Associate Director for Planning,
Evaluation, and Legislation
Health Services Administration
Parklawn Building, Room 14-33
5600 Fishers Lane
Rockville, Maryland 20857
(301) 443-2460

Chapter 19

THE ROLE OF THE INDIVIDUAL CONSUMER IN HEALTH PROMOTION AND HEALTH CARE

Purpose and Rationale

This initiative proposes to bring together the knowledge and program capabilities of the several HHS agencies engaged in health promotion research. In the context of direct involvement with the health care system, the initiative will help provide additional opportunities to study the impact of health promotion research and to suggest improvements in the delivery system itself. It is viewed as a potentially important part of the Department's overall effort to achieve the Nation's objectives in preventing disease and promoting health.

The initiative rests on two important beliefs: first, that the individual can and should assume an important--and perhaps primary--role in maintaining his or her own health, and in requesting, facilitating, and making decisions in regard to the reduction of health risk and the receipt of medical services; and second, that greatly increased emphasis should be given in health care systems to preventing health problems, rather than the present orientation toward intervention after a problem has occurred.

The Health Services Administration (HSA), through its responsibility for managing a health care system that delivers services to the Nation's high-risk populations, offers the best opportunity among several interested agencies to guide the examination of questions relevant to the potential role of the individual in health promotion and health care. These capabilities include knowledge of such key elements as the characteristics of the health problems being addressed, the range of individual perceptions toward health promotion, the concept of risk reduction, and what currently is being done in relevant areas through the research of various agencies. The responsibility for providing information relevant to health of the public at large has traditionally rested with the health care sector. It is recognized, however, that the individual must apply this knowledge to his or her own situation. This research initiative will be an important part of the Federal response to a growing interest of the public in participating in the enhancement of its own health.

The purpose of this initiative, then, is to strengthen the Department's activities in support of increased participation by individuals in their primary health care through collaboration among agencies in research which will aid the planning, implementation, and monitoring of new mechanisms and approaches to consumer involvement in health promotion. The goals are to use the findings from this research initiative to expand the delivery of health promotion services in the Department's direct service delivery program and to increase the effectiveness of primary health care by increasing both the health

awareness and participation of individuals and their self-reliance in dealing with potential health problems.

Nature of the Problem

The increasing interest and ability of individuals to take an active role in ensuring and maintaining their health status has been recognized in health promotion programs. During the past two decades, much of the hope for improving the quality and significantly extending one's life span has lain in the area of the prevention of health problems. This increased interest in prevention stems from the assumption that greater benefits are likely to accrue from our efforts to improve the health habits and environments of the American people than through further expansion of the traditional health care approach. A persuasive justification for this research initiative is stated in V.R. Fuchs' book Who Shall Live? Health Economics and Social Choice (1975):

> "The greatest current potential for improving the health of the American people is to be found in what they do or don't do to themselves. Individual decisions about diet, exercise and smoking are of critical importance and collective decisions affecting pollution and other aspects of the environment are also relevant."

To realize this potential, it is necessary for people themselves to assume responsibility for their well-being rather than rely exclusively on health care providers. However, there are difficulties. Currently, the primary health care system does not recognize, at least in any formal way, the essential role the consumer can play in health promotion through the prevention and treatment of health problems. In the majority of public and private systems, there is minimal recognition of the individual as a primary health resource.

While preventive health services are generally acknowledged to be important activities, higher priority usually is assigned services for the acute and chronically ill. However, the secondary attention and lower support given to programs directed to the prevention of health problems could have a negative impact upon national health and could increase health costs. The HSA believes that actions can be taken to help mitigate this situation through the collaborative development and application of knowledge gained from this research initiative.

We know that individuals can and do share with providers the responsibility for decisions about health care. However, people can be more active in caring for their own well-being by adapting behavior that leads to--

- basic lifestyles that are health promoting,
- prevention of health problems,
- awareness of significant warning signs of illness,
- self-diagnosis of common health conditions,

- appropriate use of medication,
- appropriate self and family treatment,
- awareness of the appropriate time to seek medical care,
- effective interaction with the professional health care system, and
- evaluation of health care received.

To increase the involvement of people in promoting their health, there is a need for the refinement and application of knowledge on how to motivate people to take responsibility for their own health, and how to intervene effectively in the social and environmental factors influencing health.

Role of HSA

One of the functions of the HHS health research planning activity is to understand the Department's magnitude and complexity and to strive for more orderly and productive relationships among its components. The research activities are not interchangeable, but derive from and are responsive to the unique missions of each of the agencies.

The HSA is the major agency responsible for direct health services within the HHS, as well as a major funding agency and source of expertise for public efforts to strengthen primary health services to unserved and underserved groups and geographical areas throughout the country. The predominant population served by HSA comprises socioeconomically depressed people who lack medical and social services, and whose prevention needs are dictated by infectious and environmentally inflicted chronic illnesses and diseases. Many of them--

- Are members of minority groups (four-fifths of those served in community health centers are blacks);
- Are from large families (27 percent of the migrant families have seven members or more);
- Have low family incomes (less than $6,000 in about 55 percent of families served by the HSA's Bureau of Community Health Services);
- Have a high rate of unemployment (among some families, as high as 26 percent).

For most of these recipients, HSA is the primary source of medical care. It is hypothesized that the involvement of the consumers of HSA services in promoting their own health will significantly improve their health status.

Currently, efforts are under way to refocus HSA's consumer health activities in terms of elements defined in Preventive Medicine, USA. Such activities would--

- Inform people about health, illness, disability, and ways in which they can improve and protect their own health, including more efficient use of the delivery system;
- Motivate people to want to change to more healthful lifestyles;
- Help them learn the necessary skills to adopt and maintain healthful practices and lifestyles;
- Foster teaching and communications skills in those engaged in educating consumers about health;
- Advocate changes in the environment that facilitate healthful conditions and healthful behavior; and
- Add to knowledge via research and evaluation concerning the most effective ways of achieving the above objectives, with special emphasis on behavioral research.

Given the missions around which HSA efforts are structured and the experi-ence gained from servicing high-risk populations, HSA is in a strong position to provide leadership in this initiative, and to assure transfer of useful results to the Nation's health care delivery system. The Public Health Service has the expertise and HSA could serve as the Department's laboratory to research and test--

- Consumer attitudes and consumer involvement in the health care process;
- Demonstration of consumer involvement theories;
- Evaluation of existing consumer participation programs and theories in terms of cost, effectiveness, consumer satisfaction, and health status outcomes; and
- Consumers' desires for increased responsibility for their own well-being.

Role of HCFA

The Health Care Financing Administration (HCFA) was established to promote the timely delivery of appropriate, quality health care to Medicare and Medicaid beneficiaries in the most efficient and cost-effective manner. HCFA's Office of Child Care administers the Early Periodic Screening, Diagnosis, and Treatment (EPSDT) program. HCFA's Office of Research, Demonstrations, and Statistics (ORDS) funds projects through its grant program in order to assist in the resolution of major health care financing policy and program issues, as well as to develop new methods for administering HCFA programs.

HCFA'S EPSDT/CHAP demonstration activities are intended to develop and test comprehensive systems that emphasize continuity of care from outreach through treatment and followup. Child health is specified as a priority area in HCFA's 1980 research and demonstration grant solicitation. This solicitation requests projects which--

- Develop mechanisms and incentives to recruit and maintain continuing care and dental providers;
- Test provider reimbursement methods to promote cost effectiveness and the development of additional services;
- Deliver comprehensive health care to teenagers including family planning and pre- and postnatal care; and
- Coordinate existing health care services offered through local, State, and Federal programs, and design administrative models for managing health care programs.

ORDS also funds projects which evaluate the effectiveness of health education programs on Federal beneficiaries.

Proposed Scope of Activities

In addition to the coordination of the research efforts on consumer involvement in health promotion, this initiative includes a project that will develop and test (in HSA facilities) techniques that will enable the consumer to use the health care system more wisely. Namely, it will help the consumer--

- To be able to identify symptoms of health problems that require professional care from those that do not,
- To seek professional care at an early stage to minimize the care needed to correct the problem,
- To be able to enter into an active partnership with health care provider to produce informed and appropriate patient behavior, and
- To prevent diseases through health-promoting behaviors such as sound nutrition.

The techniques developed should be such that they might be applied across target groups, with modifications to accommodate sociocultural differences. For example, the techniques for the urban poor should be adaptable, in principle, for use with migrants.

The project will provide data to illustrate the crucial role that the individual has in enhancing personal health through appropriate use of the

health care system and to highlight the actions the Government might take to further that role. The findings would have an impact on the issue of providing third-party reimbursement for health promotion activities as well as in training health care providers.

Relationship to HHS Health Research Principles

This initiative stems from the second Research Principle through its intent to focus on and support applied problem-oriented research aimed at disease prevention. It also relates to the third Research Principle, which requires HHS research to provide knowledge that institutions and individuals require to promote health and prevent disease.

Implementing Arrangements

This initiative will be undertaken as a cooperative effort in research planning and coordination within the Department. It will involve appropriate research activities from the Food and Drug Administration and the National Institutes of Health, particularly the National Cancer Institute and the National Heart, Lung, and Blood Institute. Other participating agencies are the Alcohol, Drug Abuse, and Mental Health Administration; National Center for Health Services Research; Center for Disease Control; Health Resources Administration; Office of Health Information and Health Promotion; Health Care Financing Administration; and Office of Human Development Services (OHDS). It will be linked to the broader effort for which the Center for Disease Control is responsible in the total area of health promotion and disease prevention. Research protocols from CDC, FDA, NIH, NCHSR, HRA, ADAMHA, NCFA, and HSA could be tested. A task force consisting of representatives from each agency that agrees to collaborate will provide advice and guidance throughout the conduct of this effort.

Resources

Many of the research activities that would be coordinated in this initiative are either under way or being planned by one or another of the proposed participating agencies. Thus, before dollar estimates can be attached to the initiative, it will be necessary to pin down actual participation by other agencies and the proposed scope of their research collaboration. It can be said, however, that for the start-up period, an initial HSA expenditure of $150,000 in fiscal year 1981 will be required to develop the program and initiate the cooperative arrangements. A resource allocation of $500,000 will be requested for implementation of the effort in fiscal year 1982.

Table 12. RESOURCES FOR FY 1980-1981
(Dollars in Thousands)

	FY 1981	FY 1981 Budget
ADAMHA*	$ 7,465	$ 9,760
CDC*	---	---
FDA*	1,591	1,700
HCFA*	320	2,000
HRA* **	965	---
HSA	---	150
OHRST/NCHSR*	---	---
NIH Total*	16,084	16,328
NCI	(2,202)	(2,316)
NHLBI	(13,882)	(14,012)

*The new research effort to be funded by these specific agencies will be potentially relevant sources of information to the project.

**The 1981 amended President's budget requested no funds for nursing research, and the Congress has not yet acted.

Chapter 20

ACCELERATED DEVELOPMENT OF NEW VACCINES

Sponsoring agency:

National Institutes of Health
- National Institute of Allergy and Infectious Diseases

Cosponsors:

Center for Disease Control
- Bureau of Epidemiology
- Bureau of Laboratories
- Bureau of State Services

Food and Drug Administration
- Bureau of Biologics

National Institutes of Health
- National Institute of Dental Research
- National Institute of Child Health and Human Development
- National Cancer Institute
- National Eye Institute

Initiative coordinator:

Dr. William S. Jordan, Jr.
Director, Microbiology and
Infectious Diseases Program
National Institute of Allergy
and Infectious Diseases
Building 31, Room 7A52
Bethesda, Maryland 20205
(301) 496-1884

Chapter 20

ACCELERATED DEVELOPMENT OF NEW VACCINES

Purpose and Rationale

The purpose of a new vaccine development initiative is to develop within the HHS a clearly identified and recognized, coordinated approach to the further conquest of vaccine-preventable diseases. New knowledge and technology emerging from basic research provide new opportunities to solve problems that have been largely insoluble with earlier technology and knowledge. The incentive for expanded efforts lies in recombinant DNA and hybridoma technologies and in the better understanding of the workings of the immune system. These new technologies permit radically different approaches to the problems of immunization. The goal of the initiative is to expedite availability of needed vaccines, and its essence is the selection of a few candidate vaccines for intense effort with additional funding so as to bring these vaccines into use at least several years earlier than might otherwise be the case.

Major emphasis will be placed on development of new vaccines against:

- Gonococcal infections
- Genital infections caused by chlamydiae and mycoplasmas
- Bacterial meningitis, particularly *H. influenzae b* infection
- *Pseudomonas aeruginosa* infection in cystic fibrosis victims
- Dental caries
- Hepatitis B and nonA-nonB hepatitis virus infections
- Infantile bronchiolitis (respiratory syncytial viruses)
- Parainfluenza virus respiratory infections (croup)
- Infantile diarrhea (rotaviruses)
- Genital and oral herpes simplex infections

Effort will also be made to improve pertussis vaccine by reducing reactogenicity.

Accelerated Development of New Vaccines

Within HHS there have been ongoing interactive programs involving more than 35 vaccines supported by the National Institutes of Health, the Center for Disease Control, and the Bureau of Biologics in the Food and Drug Administration (BOB/FDA). The National Institute of Allergy and Infectious Diseases has supported grant, contract, and intramural research and development. CDC and Bureau of Biologics efforts have been primarily intramural with some contract activity. The National Institute of Dental Research supports both intramural and extramural research against dental caries and oral-facial herpes. The National Institute of Child Health and Human Development has no direct activity in vaccines, but is involved in the study of diseases in mothers, infants, and children which are potentially preventable with vaccines. The Institute supports clinical and epidemiologic studies, as well as basic biologic approaches to defining these entities. The National Eye Institute has particular interests in infections of the cornea by herpes viruses and chlaymidiae. It supports a full range of studies on such diseases, including clinical, epidemiologic, and therapeutic research. The National Cancer Institute has a particular interest in the prevention of hepatoma with hepatitis B vaccine.

Activities include:

- Conduct and support of basic and applied research on immune mechanisms involved in diseases potentially preventable with vaccines;
- Conduct and support of basic and applied research on the antigenic composition of infectious agents causing such diseases;
- Epidemiological studies on these diseases;
- Support of research applying recombinant DNA and hybridoma technology to the isolation of antigenic components of infectious agents responsible for the stimulation of immunity and to the preparation of vaccines (e.g., production of hepatitis B virus surface antigen in E. coli cultures in in vitro systems) using these components;
- Phase I and II testing of candidate vaccines in volunteers;
- Phase III efficacy testing of promising candidate vaccines in controlled clinical trials; and
- Support and conduct of conferences and workshops to review data, examine problems, and evaluate progress.

Interactions are maintained with other organizations having interests in various vaccines. These include pharmaceutical manufacturers, the military, the Institute of Medicine of the National Academy of Sciences, and professional and voluntary societies. The interactions include scientific endeavors supported or pursued independently of HHS. There are also extensive contacts and exchanges with scientific groups from abroad, including Japan, the United Kingdom, Finland, the Soviet Union, France, and Belgium; the World Health Organization; and several international professional societies also having related interests in infectious diseases and new vaccines.

Accelerated Development of New Vaccines

It is appropriate that, at this time, HHS undertake an expanded initiative toward more rapidly bringing into use new and improved vaccines. Two reports on Health Promotion and Diseases Prevention that highlight the limitations of what can be done with existing knowledge and technology have just been published, laying the base for an increased capability in disease prevention. As measles, poliomyelitis, diphtheria, and pertussis vaccines have so clearly shown, immunization offers a most cost-effective means of control. With new technology promising the capability of solving problems that have prevented progress in the past, a definite program to exploit this technology is needed.

Industry is making large investments in recombinant DNA and hybridoma technologies, some of which are directed at vaccines. Establishment of a definitive HHS program on new vaccines should encourage industry in such efforts.

Nature of the Health Problem

Infectious diseases constitute major problems to U.S. health authorities and citizens because of high morbidity, medical costs, interference with education and productivity, and the sometimes crippling residuae. In the PHS publication "Healthy People" (No. 79-55071, 1979, p. 117), HHS estimates that infectious diseases cause at least 156 million lost work days each year and that the costs for treatment and lost productivity are $24 billion. Some 291 million illnesses due to infection are estimated to have occurred in 1975. Highlights from this and other recent HHS publications are--

- In the United States in 1977, 10 million cases of sexually transmitted diseases (STD) were reported--86 percent in 15- to 29-year-olds:

  --2.5 million cases of gonorrhea. (Of 8.7 million women from all socioeconomic levels, 4.5 percent had positive cultures in 1979.)

  --2.5 million cases of chlamydial or mycoplasmal genital infections.

  --0.5 million cases of genital herpes.

  --100,000 young women sterilized by complications of STD each year (pelvic inflammatory disease).

  --50,000 babies born with STD annually, of which 8,000 will die in a few days and 8,000 more sustain residual brain damage.

- One quarter of all visits to a physician each year derive from infection. Antibiotics are the most frequently prescribed drugs.

- Influenza and pneumonia still rate fifth or sixth annually as causes of mortality. Epidemic influenza A is clearly associated with excess mortality among the elderly, and costs of a pandemic year may total $5 or $6 billion. Costs in interpandemic years are measured in the hundreds of millions.

- Bacterial memingitis afflicts about 20,000 in the United States each year, mostly in children under age two, with a 10 to 15 percent death rate. Brain damage occurs in a large percentage of survivors. Group B streptococcus infections are a primary cause in the first three months of life, and H. influenza b is the principal cause between ages six months and two years.

- Epidemic respiratory syncytial virus infections occur in infants under one year, and are a major cause of hospitalization and mortality at that age. Also, these virus infections are a major cause of nosocomial epidemics in patients and staff of pediatric hospitals. At least 60 percent of children have had one RS infection by age two.

- Pulmonary infection caused by Pseudomonas aeruginosa is the major cause of death in individuals with cystic fibrosis. Treatment has been only moderately successful, and means for early prevention must be sought.

- Rotaviruses are a major cause of dehydrating diarrhea in very young children worldwide. In the United States, 60 to 70 percent of children are infected in the first two years of life.

- Dental caries is a universal, costly problem. The average child has 5 decayed teeth by school age and 10 by age 15. Only 1 to 2 percent of young men age 18 to 20 entering the military are caries free.

Implementing Arrangements

Current Scope of Research Activity--Existing Arrangements

In only one area is there something more than informal arrangements between the professional staffs of the several organizations involved in research programs related to vaccines. This is influenza. In 1978 the Assistant Secretary for Health appointed an interagency work group consisting of representatives of CDC, NIH, and BOB. This group developed and submitted to these agencies and ASH a synopsis on the current status of surveillance and control of epidemic influenza. A recent memorandum from ASH to the Secretary, HHS, was a product of the working group and refers to needed studies on existing influenza vaccines. It is not proposed that influenza be included in the present initiative because of the existence of the broader charge to the influenza working group.

There are frequent contacts and professional interchanges with staff of CDC and BOB on other vaccines. These professionals attend NIAID committee meetings where research on vaccines is reviewed and evaluated, leading to the award of contracts or multidisciplinary grants. A CDC member served on the recent NIAID Study Group on Sexually Transmitted Diseases. NIAID and CDC professionals have collaborated with BOB/FDA interests in vaccines against bacterial meningitis. Through such relationships the ongoing research on hepatitis B vaccine, influenza and other vaccines have been mostly collaborative endeavors.

Accelerated Development of New Vaccines

On March 18, 1980, the Acting Assistant Secretary for Health forwarded to the Secretary an action memorandum on vaccine development, production, and supply. Recommendations are made for establishment of a vaccine interagency work group primarily responsible for coordination of HHS activities related to production and use of existing vaccines, but the group would also have some responsibility for monitoring developmental activities. That charge would relate to all vaccine development, whereas the present initiative concerns only HHS efforts to expedite development of selected new vaccines.

Proposed Expanded Scope of Research Activities

Assuming that ASH will designate a series of vaccines considered to be of high priority for HHS developmental efforts, the several component agencies would respond within the general areas of their mission. NIH (NIAID) has long been considered to have the lead role in research leading to new vaccines and in demonstrating the feasibility of a new product. NIDR would have a special role related to caries and other oral dental problems, and NICHD will collaborate in the investigation of candidate vaccines in infants, very young children and mothers. NEI will identify populations suitable for investigational use of vaccines against eye infections and take the lead in planning such studies. NCI will continue its efforts to develop vaccine studies against hepatoma. The CDC has the primary role of surveillance and investigations of disease outbreaks and for application of vaccine for disease control. It would play a key role in efficacy testing and surveillance for adverse effects. The BOB/FDA has the responsibility for control of investigation of new vaccines in humans, and for licensing and control of usage of new vaccines. It would play a key role in defining the properties of a vaccine, in monitoring investigational use, in the development of tests for potency, and in the study of reactions. The pharmaceutical industry must be brought into new vaccine efforts early, since the eventual preparation and distribution of a licensed vaccine depends on industry.

More specifically, the NIAID would expand its contract program in vaccine development to--

- initiate developmental research on selected vaccines now being given only marginal attention because of lack of adequate funds--e.g., genital herpes, chlamydial and mycoplasmal vaccines, and Pseudomonas aeruginosa vaccine;
- expedite phase I, II, and III testing of candidate vaccines;
- develop acceptable adjuvants for use with vaccines yielding inadequate immune responses--e.g., parainfluenza hemaglutinin vaccines;
- determine how deficient immune responses in children under age two can be circumvented; and
- encourage other approaches to enhance resistance to the selected disease.

NIAID would also expand its intramural research activities to complement these contract activities and would solicit related collaborative agreement applications.

CDC would collaborate in the development and testing of some vaccines--e.g., hepatitis and gonococcus--and would expand its epidemiologic and laboratory research to--

- identify and develop population groups where clinical trials can be carried out;
- develop strategies for delivery and effective use of new vaccines;
- develop laboratory tests identifying susceptibility to diseases, levels of vaccine-induced immunity in populations, and mechanisms of adverse reactions;
- develop more accurate surveillance methods enabling measurement of cost/benefit of vaccines placed into use; and
- develop methods for surveillance of adverse reactions to new and unconventional vaccines.

BOB/FDA would expand laboratory studies and contract research to collaborate in the development of many vaccines--e.g., hepatitis B, nonA-nonB, and H. influenzae b and herpes, with the goal of having ready necessary tests and information for licensing and use of vaccines.

NIDR would expand research on a dental caries vaccine and collaborate in the development of a vaccine against herpes simplex viruses I and II.

NEI will increase emphasis on identifying epidemiologic entities suitable for vaccine evaluation, particularly for herpes viruses.

NCI will extend its search for epidemiologic entities suitable for evaluation of hepatitis B vaccine against hepatoma. It will also continue its considerable effort related to vaccines against herpes viruses.

NICHD would identify populations at risk and collaborate in the study of vaccine performance in such populations through--

- identification of developmental deficiencies that cause immunologic impairment in such target groups as prematures, neonates, and older children;
- study of the pathophysiology of these diseases during pregnancy and identification of causative mechanisms in individuals at high risk; and
- support of epidemiologic investigations addressing these health problems.

New Arrangements

A key link in an expanded program is the active involvement of ASH in developing and bringing into use new vaccines. For instance, both ASH and the Directors of NIH and CDC are aware of the effort being made to develop a gonococcus vaccine, but there is no present channel for them to follow progress systematically, to make sure the effort is adequately staffed and funded, and to identify any administrative or legislative roadblocks that may require departmental and legislative action. Exceptional arrangements for decision-making and communications are fully justified.

In 1980 ASH established a new PHS Interagency Group to Monitor Vaccine Development, Production, and Usage involving representation from NIH/NIAID, CDC, and BOB/FDA. This committee will have the responsibility of providing a forum for the discussion of HHS problems related to existing and new vaccines. Its reports will go to ASH and to the agency directors. These will include specific recommendations on new vaccine development and financing. It will also serve as a forum for responding to requests. A request was made to DOD for formal liaison representation because of the potential for vaccine development under military auspices and the needs for coordination in the usage of many vaccines in the civilian and military populations.

A different kind of interagency work group is needed for this initiative. This must be a group of technically competent professionals with expertise in all aspects of vaccine development and testing that are intimately involved in the efforts of their respective agencies on the initiative. They must have extensive contacts in academic and international circles and in government and industry; must keep current on progress in vaccine development under auspices other than HHS and DOD; and must be able to take advantage of all new technical advances. The team would have the following responsibilities:

- Develop a technical plan for the development of each individual vaccine through phase III efficacy trials;
- Monitor the progress of development of each vaccine, identifying obstacles as these arise, seeking solutions, altering technical plans as needed;
- Decide when development is stalled and cannot progress without new technology;
- Decide when technological progress makes development of still other vaccines possible; and
- Decide what priority should be given to each vaccine plan if funds are inadequate for the whole.

This team should be chaired by the coordinator of the initiative and should meet every three months. After each meeting, the team should prepare a progress report, proposing and recommending any action necessary by ASH or agency officials, recommending deletion of vaccines on the initial list, and incorporation of other vaccines to the list. Problems with funding or

staffing that retard the effort would be identified in these reports. Copies of the reports would go to ASH (designated office); the Directors of NIH and CDC; the Commissioner of Food and Drugs; and the Directors of NIAID, NIDR, NICHD, NEI, NCI, and BOB/FDA. The initial report would append the development plans, projected timetable, and estimated costs for each vaccine. This would be updated annually.

Progress

The Institute has held discussions with the Institute of Medicine and is expecting a proposal from them as one step in implementing this initiative. The IOM has been invited to undertake the review of potentially vaccine-preventable diseases from the standpoint of socioeconomic and medical needs and to assess the cost benefits of vaccines for each of these diseases. It also needs to assess the interest of industry in developing each vaccine and the prospective roles of government and the private sector. These studies are expected to get under way in early calendar 1981 with the diseases listed herein given first priority. Eventually all vaccine-preventable diseases will be reviewed in this manner, including those where the exposure may only be under special circumstances (e.g.--veterinarians, laboratory workers) or in the developing countries.

The Institute also arranged for its Advisory Committee to review a proposal for efficacy testing of a candidate gonococcus vaccine and will follow these tests with interest if they proceed.

Table 13. RESOURCES FOR FY 1980-1981
(Dollars in Thousands)

	FY 1980	FY 1981 Budget
CDC	$ 608	$ 608
FDA	4,500	4,800
NIH Total	10,598	10,619
NCI	(1,100)	(1,100)
NEI	(941)	(1,035)
NIAID	(5,290)	(4,911)
NICHD*	(2,592)	(2,673)
NIDR	(675)	(900)

*Figures represent research related to potentially vaccine-preventable diseases in mothers and their infants.

Chapter 21

RESEARCH TRAINING

Sponsoring agency:

National Institutes of Health

Cosponsors:

Alcohol, Drug Abuse, and Mental Health Administration

Health Resources Administration
Division of Nursing

Office of Health Research, Statistics, and Technology
National Center for Health Services Research

Initiative coordinator:

Dr. Doris Merritt
Special Assistant to
the Director, NIH
National Institutes of Health
Building 1, Room 118
Bethesda, Maryland 20205
(301) 496-9743

Chapter 21

RESEARCH TRAINING

Purpose and Rationale

This proposed initiative represents a cooperative effort among four agencies of the Department: NIH, ADAMHA, the Division of Nursing in HRA, and the National Center for Health Services Research in OHRST. Its purpose is to assure on a continuing basis a critical mass of well-trained scientists to carry out the research needed to meet national health goals.

As noted in the initiative for "Stabilizing the Science Base: Research Project Grants," there is a close and reciprocal relationship between the continued productivity of research and the availability and replenishment of the supply of well-trained investigators. Their availability wholly determines the ability to conduct research. We know that trainees with Federal support are able to complete their training more effectively and in minimum time. We can also predict that postdoctoral trainees will pursue a more productive research career as a result of their advanced training. At the predoctoral and immediate postdoctoral levels, the individual becomes imbued with the fundamental concepts and techniques of the scientific method. The training programs also provide the prime opportunity for the research agencies to maintain and strengthen institutional training environments so that the numbers and kinds of investigators being trained will be prepared to conduct research in areas of national need.

Currently, the subset of the postdoctoral fellow population of greatest concern to the biomedical and behavioral scientific community is that composed of physicians, or other persons with an equivalent degree, who seek additional training to become clinical investigators. Responsibility for the conquest of disabilities which afflict mankind rests ultimately on the shoulders of well-trained clinicians, who must examine the value of laboratory results in human beings.

For the nursing community, the principal concern is to train a sufficient number of investigators able to assess the impact of innovative nursing interventions in certain critical areas. These include how to increase the well-being and effective social functioning of persons suffering from chronic and debilitating diseases; how to maximize quality of care while minimizing costs; and assessing the role, effectiveness, and competence of nurses in providing certain aspects of primary, secondary, and tertiary care. Also, there is a need for individuals with sophisticated training in analyzing problems in health care planning and the delivery of health services.

Nature and Magnitude of the Health Problem

There has been a progressive decline over the last eight years in the number of research trainees supported under NRSA authorities. Recently the decision to stabilize research project grants required a readjustment in priorities within NIH resulting in cutbacks in research training. The number of NIH trainees, for example, dropped from 11,200 in 1979 to 9,300 in the 1981 President's budget,* with no new starts envisioned for 1981. Within ADAMHA, there has been a reduction from 1,600 trainees in 1979 to 1,400 trainees in the President's 1981 budget. While the research training program will survive a temporary cutback, there is substantial consensus among agency program administrators and the research community that some restoration of resources and long-term predictability are essential to the health of the research enterprise.

Similarly, the need for individuals trained in the various fields of health services research is becoming acute. There has been relatively little Federal support during the past decade for graduate-level training in this area. The reports of the National Academy of Sciences referred to in the next-to-last paragraph of this initiative consistently point to the need for, and advantages of, trained investigators with a background in the theory and methods of health services research. As noted in the 1977 report, the Nation "may ultimately lack the availability of personnel whose expertise is of sufficient caliber to tackle sophisticated research problems related to health care planning."

Relationship to the Health Research Principles

This initiative relates to the fourth Health Research Principle, to sustain and enhance present research capabilities--in particular, human resources--to assure future health gains. The initiative also touched on an aspect of the fifth Health Research Principle, which states that the "funding and training of young investigators are essential to the future of health research."

Implementing Arrangements

What, then, are appropriate levels of support for research training? The question is a difficult one, particularly since the quality of program and the field chosen for support are crucial. The legislation establishing the NRSA program (P.L. 93-348) mandated a continuing study of the Nation's personnel needs and training for biomedical and behavioral research to be undertaken by the National Academy of Sciences. The Academy has addressed these difficult questions in a feasibility study, four full reports, and most recently, an interim 1979 report. Actual training program data for NIH, ADAMHA, and HRA for FY 1980 and 1981 are shown in relation to Academy recommendations.

*The 1981 continuing resolution provides for approximately the same number of trainees in 1981 as in 1979.

Table 14. NRSA EXPENDITURES FOR FY 1980-1981
(In Millions)

	FY 1980	FY 1981
ADAMHA	$ 20.8	*
NIH	175.5	*
HRA/DN	1.0	*
NAS Recommendation	$ 207.4	$ 218.8

*Not available.

Chapter 22

PREVENTION OF BIRTH DEFECTS

Sponsoring agency:

National Institutes of Health
- National Institute of Child Health and Human Development

Initiative coordinator:

Dr. Norman Kretchmer
Director
National Institute of Child Health and Human Development
Building 31, Room 2A03
Bethesda, Maryland 20205
(301) 496-3454

Proposed participating agencies:

National Institutes of Health
- National Institute of Environmental Health Sciences
- National Institute of Neurological and Communicative Disorders and Stroke
- National Institute of Allergy and Infectious Diseases
- National Eye Institute
- National Institute of General Medical Sciences
- National Library of Medicine
- National Heart, Lung, and Blood Institute
- National Institute of Dental Research
- National Cancer Institute

Center for Disease Control

Food and Drug Administration

Health Services Administration
- Office for Maternal and Child Health

Alcohol, Drug Abuse, and Mental Health Administration

Office of Health Research, Statistics, and Technology
- National Center for Health Statistics

Chapter 22

PREVENTION OF BIRTH DEFECTS

Purpose and Rationale

The proposed initiative will be undertaken as a cooperative effort within the Department. It will involve 9 of the 11 NIH Institutes and the National Library of Medicine at NIH, the Center for Disease Control, the Food and Drug Administration, the Health Services Administration, the Alcohol, Drug Abuse, and Mental Health Administration, and the National Center for Health Statistics. It will serve to coordinate Federal research programs on the cause and prevention of birth defects. This initiative will also be related to the existing initiative "Prevention of Reproductive Effects Due to Workplace Hazards" through close coordination and cooperation between the NICHD and NIOSH program staffs. Although the two initiatives differ in scope and content, collaborative efforts will be encouraged in order to maximize benefits to research on the prevention of birth defects due to all causes, including workplace hazards.

Nature and Magnitude of the Health Problem

Birth defects are defined as all those inborn structural, functional, biochemical, and behavioral anomalies that are initiated prior to birth or shortly thereafter and that cause immediate or delayed abnormality. Causes of abnormal development include the genetic makeup of the individual, exposure to environmental factors, and individual life style.

Only 30 percent of birth defects are of known cause. In some manifestations, two or more teratogens may work together to produce an effect on the fetus.

Each year 250,000 infants, or 7 percent of all those born alive, have mental or physical defects. One-third of all admissions to pediatric hospitals result from abnormal gene-environment interaction. It is estimated that the total loss in years of life from birth defects due to genetic causes are 3.5 times that due to cancer, 6.5 times that due to heart disease, and 8 times that due to stroke. In 1975, treatment of birth defects through State services for crippled children cost more than $161 million. To that sum must be added estimated costs of $3 billion for hospital stays and $200 million for private physician visits.

In 1975, 17 percent of all deaths in children between 1 and 4 years of age were attributed to congenital defects. These can range from mild to severe. They include muscular and skeletal abnormalities, blindness and deafness, heart and circulatory difficulties, mental retardation, diabetes,

speech problems, and defects of the nervous, digestive, endocrine, genito-urinary, and other body systems.

Relationship to the Health Research Principles

The proposed initiative on birth defects embodies Health Research Principles as follows:

- Basic and applied research are needed to determine the genetic and environmentally induced causes and mechanisms of congenital malformations, gross intrauterine malformations, and fetal and infant death.

- Fundamental knowledge on the causes of reproductive hazards and birth defects can be applied to improving health care through studies on educational programs designed, for example, to deter use of over-the-counter drugs, alcohol, and cigarettes during pregnancy and to improve genetic counseling services. In addition, the findings will be used as the basis for regulatory decisions and control measures.

Implementing Arrangements

Current Research Activity

The following NIH Institutes and other HHS agencies support research on birth defects:

The National Institute of Child Health and Human Development. The NICHD supports research on the causes of birth defects and on the development of methods to prevent, alleviate, and treat them. Studies are supported on both normal and abnormal development in the basic disciplines of developmental biology, genetics, and teratology in combination with clinical studies, population genetics, and behavioral teratology. Emphasis is also placed upon biochemical and metabolic components of inborn errors of metabolism and on cytogenetic studies with special concern for Down's syndrome. Investigations are supported on the development of the reproductive systems to allow better understanding of the mechanisms associated with gametogenesis and to identify the contributions to growth and differentiation that gametes bring to the process of fertilization. In FY 1979 the NICHD expended $23.7 million for research on birth defects.

National Institute of General Medical Sciences. Research directly relevant to the development of congenital malformations is supported by the NIGMS through its genetics and pharmacological programs. This research is concerned with genetically determined malformations such as chondrodystrophies, teratogenic effects of maternal hyperthermia, the fetal alcohol syndrome, warfarin embryopathy, and the morphologic and functional effects on the fetus of maternal exposure to hormones, including sex hormones and insulin. In general, these studies are supported as part of various center grants as illustrative or model examples of general biologic problems.

National Eye Institute. The NEI supports research relevant to a broad range of developmental and hereditary disorders of the eye and visual system.

Examples include retinal degenerations, including retinitis pigmentosa, inherited corneal dystrophies, congenital cataract, congenital glaucoma, and developmental sensory and motor disorders of vision, such as strabismus and amblyopia. Research supported by the NEI on developmental anomalies and hereditary disorders of the eye encompasses a variety of scientific disciplines, with major emphasis on embryology, biochemistry, anatomy and morphology, and neurobiology. In FY 1981 the NEI will spend an estimated $13 million on research related to genetic disorders alone.

National Heart, Lung, and Blood Institute. The NHLBI supports approximately $3 million in grants for research on congenital heart disease. Studies emphasize the history and mechanisms of congenital heart defects and cardiovascular teratogenesis, the etiology and treatment of congenital heart disease, the management of patent ductus in premature infants, and cardiovascular pharmacodynamics and other animal studies of the developing heart.

National Institute of Dental Research. The overall objective of the NIDR research program is to reduce the frequency of congenital craniofacial anomalies and minimize their impact on the individual and society. Research and research training are supported relating to the prevention, diagnosis, etiology, and treatment of craniofacial malformations. Emphasis is placed upon cleft lip/palate, severe malrelations of teeth and jaws, and other congenital anomalies that involve oral or craniofacial structures.

National Library of Medicine. A human genetics knowledge base is being developed by the Lister Hill National Center for Biomedical Communications of the NLM. Research encompasses contemporary computer and communications systems to explore methods for efficient literature identification, knowledge acquisition, knowledge-base construction, representation, and access. The goal is to contribute to more access and use of available genetic biomedical information needed in solving daily problems of diagnosis, prognosis, and treatment.

National Institute of Environmental Health Sciences. Ongoing research at the NIEHS related to congenital malformations falls into three areas. The first involves the study of the distribution and metabolism of common environmental chemicals in fetal, maternal, and newborn animals as contributing factors in birth defects. In the second area, the immediate manifestations of toxic effects from environmental agents (chemicals, gases, microwaves, and noise) are investigated in pregnant animals, with emphasis on the mechanisms of action. The third area involves long-term, latent toxic effects resulting from prenatal exposure to environmental agents. These three areas of research are supplemented by work with tissue culture systems as well as active programs in genetics and environmental mutagenesis.

National Cancer Institute. The NCI supports research related to congenital defects through studies on embryology, toxicology, and teratogenesis.

National Institute of Neurological and Communicative Disorders and Stroke. The NINCDS funds and conducts research on the neurobiological, genetic, and environmental aspects of developmental disorders of children, including cerebral palsy and other motor disorders; autism and behavioral disorders; mental retardation and learning disorders; central nervous system birth defects, such

as spinabifida, hydrocephalus, macrocephaly, microcephaly; and multiple malformations of the eye, mouth, genitourinary system, and heart. Research is also supported on genetic disorders, such as inherited metabolic diseases--Gaucher's disease (lipid storage defect), Tay Sachs disease, and mucopolysaccharide storage disease.

National Institute of Allergy and Infectious Diseases. The NIAID supports research on viral infections (such as cytomegalovirus and toxoplasma) in pregnant women and their possible role in the intrauterine development of defects in the fetus.

Alcohol, Drug Abuse, and Mental Health Administration. Programs in each of the three Institutes of the ADAMHA have relation to the proposed initiative. The National Institute of Alcohol Abuse and Alcoholism is the focal point for research on the fetal alcohol syndrome. Research on drug-induced hazards to reproduction is conducted by the National Institute on Drug Abuse, and behavior teratology is studied through programs of the National Institute on Mental Health.

Center for Disease Control. The CDC is proposed as a participant in the initiative as a source of epidemiologic data concerning toxic hazards in the environment and workplace and analyses of chromosomal damage associated with toxic exposures. The CDC/NIOSH conducts epidemiologic and laboratory investigations of effects on reproductive outcomes of exposure to toxic substances. It has singled out reproductive effects of workplace hazards for special emphasis in its research grants program and is the lead agency for the health research initiative in that area.

Food and Drug Administration. Research on effects of new and existing drugs and substances is supported to determine possible teratogenic effects on fetal development and pregnancy outcome.

Health Services Administration. The Office for Maternal and Child Health is included in the proposed initiative specifically for coordination in areas of health care and genetic counseling.

The National Center for Health Statistics. The NCHS collects and coordinates statistical and epidemiologic data on the effects of environmental agents on reproduction and on the incidence and prevalence of congenital defects among infants and children. P.L. 95-623 names the NCHS as lead coordinator for the identification of environmental factors contributing to birth defects and genetic damage.

New Arrangements

To carry out this initiative, a committee is proposed that will include representatives from each of the participant Institutes of NIH and ADAMHA and from CDC/NIOSH, FDA, HSA, and NCHS. Chaired by the NICHD, the committee will serve to--

- Identify existing programs and mechanisms to facilitate coordination and cooperation,

- Identify potential new areas for individual and collaborative research, and
- Develop a detailed plan for the accomplishment of the initiative which incorporates budget and program data.

Chapter 23

RESEARCH ON PREVENTION AND CONTROL OF HYPERTENSION

Sponsoring agency:

National Institutes of Health
National Heart, Lung,
and Blood Institute

Initiative coordinator:

Dr. Robert I. Levy
Director, National Heart, Lung,
and Blood Institute
Chairman, Interagency
Technical Committee
National Institutes of Health
Building 31, Room 5A52
Bethesda, Maryland 20205
(301) 496-5166

Proposed participating agencies:

Health Services Administration
Bureau of Community Health Services

Health Resources Administration
Bureau of Health Manpower

Office of Assistant Secretary for Health
National Center for Health Services Research
National Center for Health Statistics

Food and Drug Administration
Bureau of Drugs
Bureau of Foods

National Institutes of Health
National Institute on Aging

Health Care Financing Administration

Center for Disease Control
Bureau of Health Education

Chapter 23

RESEARCH ON PREVENTION AND CONTROL OF HYPERTENSION

Purpose and Rationale

The purpose of this initiative is to increase the scope of hypertension prevention and control research within the Department of Health and Human Services, to increase the number of agencies active in the field, and to coordinate their work. This effort will pursue the objective of preventing deaths and disabilities associated with uncontrolled hypertension, decreasing the costs of control in the health care system.

The rationale is a simple one. Since initiation in 1972 of the National High Blood Pressure Education Program, coordinated by the National Heart, Lung, and Blood Institute, significant progress has been made in achieving wide adoption of the state-of-the-art in hypertension control. Wider adoption is possible and is actively being pursued. However, recent data analysis suggests that control measures alone can reduce the hypertension-associated risks of only 60 percent of the hypertensive population to near normal level at any point in time. Primary prevention measures, which are not currently possible but are on the threshold of applicability in several areas, have the potential to achieve higher percentages of persons at reduced risk, at even higher cost/benefit ratios than control measures. At the same time, further research in control therapy and care delivery modes will still be required because application of primary prevention measures will not help some segments of the population, including those with long-established hypertension.

Nature and Magnitude of the Problem

Some 60 million Americans are at increased risk of stroke, heart disease, and kidney failure due to elevated blood pressure. As much as 95 percent of high blood pressure (HBP) has no known cause or cure. Nonetheless, HBP can be controlled in most persons using available therapies, resulting in a well demonstrated risk reduction. Most studies also indicate a small but positive cost benefit, provided that care follows reasonable recommendations.

Because the cause of most diagnosed HBP is unknown, application of primary prevention measures is not currently possible; but some promising avenues exist:

- Further pursuit of recent research on sodium flux abnormalities in the red blood cells of certain people may allow intelligent, beneficial counseling on sodium intake for persons sensitive to sodium.

- Excess weight seems to be a risk factor for HBP, but not all obese persons develop the condition. Although general recommendations can be made to the public now, further research is needed to determine why blood pressure in certain persons is affected by weight.

- Psychological modalities (biofeedback, relaxation training, etc.) also show some promise as HBP control measures, perhaps even as primary prevention measures for some patients. Regular vigorous exercise has been shown to have a direct effect on blood pressure in some people, as well as playing an energy balance role in weight control. To date, however, both the scale and quality of research on these modes has been inadequate to assess their utility and benefits.

Even with several important questions pending, however, it is clear that controlling HBP is effective secondary prevention against cardiovascular and renal disease. Blood pressure elevations are detectable simply and at low cost. Drug therapy, dietary therapy, and possibly selected psychological measures reduce blood pressure and risk, and are now available nationwide.

The National High Blood Pressure Education Program (NHBPEP), a nationwide effort to improve HBP control, has been operating since 1972. Some appreciable changes have been observed during this time. Americans are increasingly aware that HBP is a health threat and that treatment is available to control it. Patient visits and prescriptions for hypertension have risen well above previous norms. Although no reliable national data are available, local or regional studies indicate larger increases in the number of persons aware of their condition, under treatment, and under control. Associated death rates have been falling dramatically. The stroke death rate, which previously was dropping slowly at about 1 to 1.5 percent a year, has plummeted since 1972 at a rate of 5 percent a year.

This progress, although welcome and sizable, does not indicate complete success. Many problems remain to be resolved. Minority and rural populations have been less successful at HBP control, largely due to poorer access to health care. It has proved difficult to achieve provider action and patient response on issues of adherence to treatment regimens. Progress has been made in getting HBP treated to specific-goal blood pressure levels, but this approach is not yet universally accepted.

Given the results of recent clinical trials, effective use of dietary management must become much more widespread than at present. Providers and patients must be taught new skills required by these regimens.

A tendency to evolve a HBP care system separate from the general care system must be overcome. There is lack of reimbursement for necessary patient counseling. Legal barriers prevent or slow adoption of needed, appropriate roles by some providers. Major elements are lacking for both national and State data bases to aid planning and monitoring of progress. There is a lack of marketing acumen among providers, preventing stimulation of effective, appropriate health care system use by consumers.

Effect of the Initiative on the Health Problem

The effect of the proposed research will be reduction of death and disability due to uncontrolled hypertension and lower health care costs attributable to cardiovascular disease. Each of the problem areas discussed in the previous section, when aggressively addressed, can be improved.

Within the Department of Health and Human Services, the effect will be increased interagency communications leading toward more effective research management.

Relation to Health Research Principles

This initiative relates to several of the major Health Research Principles approved recently by the Secretary of HHS as underlying the Federal commitment to health research. First, it relates to the need for steady support of the biomedical spectrum, beginning with stabilization of the science base and continuing with the development of the knowledge base for direct attack on health problems. The initiative will seek to elucidate the physiological and psychological mechanisms underlying blood pressure regulation.

Secondly, it relates to applications. For example, the Hypertension Detection and Follow-up Trials demonstrate that prescribing a vigorous, well-controlled, systematic treatment program for hypertensive patients and that treating mild hypertension may reduce the incidence of premature deaths in all age and ethnic groups.

Thirdly, it relates to knowledge transfer, addressing the need to generate the knowledge base for the use of the individual consumer in health promotion and health care. The knowledge developed through the initiative will help establish preventive measures and formulate approaches to protect the public from a major cardiovascular disease risk factor.

Finally, the initiative is concerned with the need to sustain research capabilities through training.

Planning for the initiative will attempt to assure that all resources required to carry out the program are available, including trained scientists, physical plants, and funds.

Implementing Arrangements

The following agencies have research or research-related activities in hypertension:

National Heart, Lung, and Blood Institute
Health Services Administration/Bureau of Community Health Service
Health Resources Administration/Bureau of Health Manpower
Center for Disease Control/Bureau of Health Education
Veterans Administration
Health Care Financing Administration

Food and Drug Administration
National Center for Health Statistics
National Institute on Aging
National Center for Health Services Research

The primary purpose of the proposed initiative is to increase resource investment and coordination for the hypertension research questions with clearly established need. When the needs have been addressed, the secondary purpose is to stimulate effective investigation of new questions.

Existing Arrangements

The NHLBI is Congressionally mandated to coordinate Federal heart, lung, and blood research through an Interagency Technical Committee (IATC). Current membership of the IATC includes the Center for Disease Control (Bureau of Laboratories), Rehabilitiation Services Administration, National Institute of Mental Health, Veterans Administration, Department of Agriculture, National Science Foundation, Office of the Surgeon General, Social Security Administration, National Aeronautics and Space Administration, National Center for Health Care Technology, Health Resources Administration, Health Services Administration, National Institutes of Health, Department of Transportation, Food and Drug Administration, Environmental Protection Agency, and Department of Energy. In recent years, working groups of the parent IATC have resulted in increased interaction and benefit. To manage the proposed initiative, a Hypertension Working Group would be formed under the aegis of the IATC. The Working Group would serve as a mechanism for policy consensus, activities coordination, and a regular communication forum on problems and progress of the effort.

Proposed Scope of Research

Research is proposed in five broad categories:

- Biomedical research

  --impact of sodium intake restriction as therapy and as a selective prevention approach;

  --weight control (energy balance) as therapy and as a selective prevention approach; exercise and nutrition must be examined together in this context;

  --isolated systolic hypertension therapy benefits, especially among the elderly who have the highest prevalence of this condition.

- Behavioral research

  --psychological approaches to blood pressure control as therapy and as selective preventive steps;

--improvement of regimen adherence approaches, including examination of both provider and patient roles.

- Health care services delivery research

--cost-effective patient tracking systems;

--improved, interdisciplinary record-keeping systems;

--community program demonstrations, especially those aimed at improving access to health care for minority populations.

- Education/marketing research

--improved approaches to continuing medical education for provider groups;

--improved teaching of chronic disease management, patient counseling, and preventive medicine in professional schools;

--improved evaluation modes for mass media educational materials;

--improved modes for assessing population knowledge and behavior (baseline and change trends) to plan educational efforts.

- Data base improvement

--development of more sensitive and timely HBP prevalence data and HBP control-status data in the Nation;

--development of affordable approaches for periodic assessment of the incidence of hypertension, stroke, heart attack, congestive heart failure, and renal failure;

--development of means to acquire national population trend data on sodium consumption (measured as excretion) and other relevant dietary measures.

Proposed Relationships

Research Area \ Agency	NHLBI	HSA/BCHS	HRA/BHM	CDC/BHE	VA	HCFA	FDA	NCHS	NIA	NCHSR
Biomedical	X				X		X		X	
Behavioral	X				X		X		X	X
Care Delivery	X	X			X	X				X
Education	X		X	X		X	X		X	X
Data Base	X	X				X		X		

APPENDICES

APPENDIX A

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MARYLAND 20205

February 5, 1980

MEMORANDUM TO: HEW Steering Committee

From: Chairman

On January 29 the Secretary approved release of the draft HEW Health Research Planning Document, and requested various followup actions by the Steering Committee. (See attachments for the memorandum from the Secretary to Dr. Richmond.) In accordance with the Secretary's wishes, we are now having the document printed in multiple copies so that it can be distributed for comment to all who participated in the planning process. Copies for this purpose should be available by the end of the month. The Institute of Medicine is being asked for a separate evaluation of the report, including development of recommendations for further action by the Department. I will be meeting with Dr. Richmond to discuss how the Steering Committee should proceed to undertake the new assignments from the Secretary.

This prepublication copy of the document is being sent to you because the Appropriations Committees asked for and received copies in anticipation of our appropriations hearings. Those hearings are underway with the Senate and will begin in the House in the next two weeks. You may be queried on this document and the role your agency plays in some of the initiatives. Thanks very much.

D S Fredrickson

Donald S. Fredrickson, M.D.
Director, NIH

Enclosures

THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE
WASHINGTON, D.C. 20201

JAN 2 9 1980

MEMORANDUM FOR THE ASSISTANT SECRETARY FOR HEALTH

SUBJECT: HEW Health Research Planning

I have recently received from Dr. Donald Fredrickson, Chairman of the HEW Steering Committee for the Development of Health Research Strategy, a report on HEW's health research activities. I am impressed by the thought and dedication that have gone into the preparation of this draft document.

Because the planning document is so important to the future of our research activities, I have asked that comments on it be solicited from the Office of Management and Budget, the Office of Science and Technology Policy, appropriate Congressional committees and individuals who participated in its development. In addition, the Institute of Medicine will conduct a thorough review of the report, including the development of recommendations for further action by the Department.

I am now asking that you work with Dr. Fredrickson and the members of the Steering Committee to:

1. Carefully evaluate all comments and revise the planning document as necessary.

2. Assess the proposed initiatives and their implications for future fiscal year budgets. Your evaluation should both set priorities among the initiatives and indicate the relative importance of these proposals compared to other health research within your agencies and to other PHS programs.

3. Investigate how we can integrate this process into our ongoing HEW health research planning and budget activities.

Our objective must be to build on our accomplishments to date so that we can convincingly demonstrate to both the public and the research community HEW's commitment to the support of health research.

Please report back to me by June 15.

Pat—Robert Harris

Patricia Roberts Harris

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MARYLAND 20014

February 19 (or 22), 1980

Dear (SEE ATTACHED LIST OF ADDRESSEES)

At the request of Secretary Harris, I am enclosing for your review the report "HEW Health Research Planning: Current Efforts and Proposed Initiatives." This document represents the second phase of the process of developing a health research strategy for the Department of Health, Education, and Welfare--a process that has been characterized throughout by commitment to public and research community involvement. The first phase of this effort, completed in August 1979, resulted in a set of principles to guide the Department in its conduct and support of health research programs.

The attached planning document is the product of the HEW Steering Committee, consisting of the Assistant Secretary for Health and all Public Health Service agency heads, the Assistant Secretary for Management and Budget, the Assistant Secretary for Planning and Evaluation, and the Administrator of the Health Care Financing Administration. At the Secretary's request, the Director of the National Institutes of Health serves as Chairman.

The report is in two parts. First, each of nine agencies within HEW provides a self-analysis of how it is organized to conduct and support health research. The second part includes eleven "proposed initiatives," which are examples of interagency cooperation in addressing some of the most important problems in health science facing America and the world today. In the first of these, NIH and the Alcohol, Drug Abuse, and Mental Health Administration propose multi-year stabilization of the level of investigator-initiated research grants. This initiative was reflected in the 1981 President's budget for health research. Other initiatives include: The National Toxicology Program, in which HEW and several other Federal agencies coordinate research to provide critically needed information on chemicals in the environment; population research; nutrition research; smoking and behavior; the health effects of radiation; and so on.

Each initiative relates to one or more of the recently approved health research principles. Each involves voluntary agreement among two or more HEW agencies that share mission interest in a particular health problem and see opportunities to increase the effectiveness of research on that problem through planning and coordination. The initiatives are proposed as a new and supplementary element in HEW health research budgeting.

Publication of this planning document does not by itself commit the support of the Department or the Administration to any particular levels of research activity or to the new initiatives proposed. While some of these initiatives will be highlighted in the budget process, they will not be accorded automatic priority in budget decisions. They must still compete with other research activities and with each other.

Secretary Harris has directed the HEW Steering Committee to evaluate all comments carefully and to revise the planning document as necessary. She has also asked the Committee to assess the proposed initiatives and their implications for future budgets. The Committee will then set priorities among the initiatives, and indicate their relative importance compared with other health research efforts of the Department. The Secretary has further directed the Committee to investigate how best to integrate this planning process into ongoing HEW planning and budget activities.

In light of the Secretary's request, I would appreciate any comments you may have concerning this planning document. I hope you will share my conviction that it provides an excellent framework for discussion and further planning of health science in the United States.

Sincerely yours,

Donald Fredrickson

Donald S. Fredrickson, M.D.
Director

Enclosure

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MARYLAND 20205

February 19, 1980

Dr. Frank Press
Director
Office of Science and Technology Policy
Executive Office of the President
Washington, D.C. 20500

Dear Frank:

At the request of Secretary Harris, I am enclosing for your review the report "HEW Health Research Planning: Current Efforts and Proposed Initiatives." This document represents the second phase of the process of developing a health research strategy for the Department of Health, Education, and Welfare--a process that has been characterized throughout by commitment to public and research community involvement. As you know, the first phase of this effort, completed in August 1979, resulted in a set of principles to guide the Department in its conduct and support of health research programs.

The attached planning document is the product of the HEW Steering Committee, consisting of the Assistant Secretary for Health and all Public Health Service agency heads, the Assistant Secretary for Management and Budget, the Assistant Secretary for Planning and Evaluation, and the Administrator of the Health Care Financing Administration. At the Secretary's request, the Director of the National Institutes of Health serves as Chairman.

The report is in two parts. First, each of nine agencies within HEW provides a self-analysis of how it is organized to conduct and support health research. The second part includes eleven "proposed initiatives," which are examples of interagency cooperation in addressing some of the most important problems in health science facing America and the world today. In the first of these, NIH and the Alcohol, Drug Abuse, and Mental Health Administration propose multi-year stabilization of the level of investigator-initiated research grants. This initiative was reflected in the 1981 President's budget for health research. Other initiatives include: the National Toxicology Program, in which HEW and several other Federal agencies coordinate research to provide critically needed information on chemicals in the environment; population research; nutrition research; smoking and behavior; the health effects of radiation; and so on.

Each initiative relates to one or more of the recently approved health research principles. Each involves voluntary agreement among two or more HEW agencies that share mission interest in a particular health problem and see opportunities to increase the effectiveness of research on that problem through planning and coordination. The initiatives are proposed as a new and supplementary element in HEW health research budgeting.

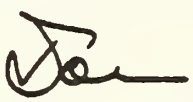
Publication of this planning document does not by itself commit the support of the Department or the Administration to any particular levels of research activity or to the new initiatives proposed. While some of these initiatives will be highlighted in the budget process, they will not be accorded automatic priority in budget decisions. They must still compete with other research activities and with each other.

Secretary Harris has directed the HEW Steering Committee to evaluate all comments carefully and to revise the planning document as necessary. She has also asked the Committee to assess the proposed initiatives and their implications for future budgets. The Committee will then set priorities among the initiatives, and indicate their relative importance compared with other health research efforts of the Department. The Secretary has further directed the Committee to investigate how best to integrate this planning process into ongoing HEW planning and budget activities.

You have kept abreast of these planning activities and we have benefited from your reactions to some of the products.

In light of the Secretary's request, I would appreciate any further comments you may have concerning this planning document. I hope you will share my conviction that it provides a useful framework for discussion and further planning of health science in the United States.

Sincerely yours,



Donald S. Fredrickson, M.D.
Director

Enclosure

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MARYLAND 20205

March 3, 1980

MEMORANDUM TO: Participants in the Development of a Health Research Strategy for HEW

Subject: Report and Public Record on HEW Health Research Planning

At the request of Secretary Harris, I am enclosing for your review the report "HEW Health Research Planning: Current Efforts and Proposed Initiatives." This document represents the second phase of the process of developing a health research strategy for the Department of Health, Education, and Welfare--a process that has been characterized throughout by commitment to public and research community involvement.

The first phase of this effort, completed in August 1979, resulted in a set of principles to guide the Department in its conduct and support of health research programs. You will find enclosed a compilation of documents relating to the development of those principles--a second volume of the "public record" of all significant actions preparatory to the drafting of a health research plan.

Throughout the development of the planning document, responsibilities were assigned to the HEW Steering Committee. This group consists of the Assistant Secretary for Health and all Public Health Service agency heads, the Assistant Secretary for Management and Budget, the Assistant Secretary for Planning and Evaluation, and the Administrator of the Health Care Financing Administration. At the Secretary's request, the Director of the National Institutes of Health serves as Chairman of the Committee.

The report is in two parts. First, each of nine agencies within HEW provides a self-analysis of how it is organized to conduct and support health research. The second part includes eleven "proposed initiatives," which are examples of interagency cooperation in addressing some of the most important problems in health science facing America and the world today. In the first of these, NIH and the Alcohol, Drug Abuse, and Mental Health Administration propose multiyear stabilization of the level of investigator-initiated research grants. This initiative was reflected in the 1981 President's budget for health research. Other initiatives include: The National Toxicology Program, in which HEW and several other Federal agencies coordinate research to provide critically needed information on chemicals in the environment; population research; nutrition research; smoking and behavior; the health effects of radiation; and so on.

Each initiative relates to one or more of the recently approved health research principles. Each involves voluntary agreement among two or more HEW health agencies that share mission interest in a particular health problem and see opportunities to increase the effectiveness of research on that

problem through planning and coordination. The initiatives are proposed as a new and supplementary element in HEW health research budgeting.

Publication of this planning document does not by itself commit the support of the Department or the Administration to any particular levels of research activity or to the new initiatives proposed. While some of these initiatives will be highlighted in the budget process, they will not be accorded automatic priority in budget decisions. They must still compete with other research activities and with each other.

Secretary Harris has directed the HEW Steering Committee to evaluate all comments carefully and to revise the document as necessary. She has also asked the Committee to assess the proposed initiatives and their implications for future budgets. The Committee will then set priorities among the initiatives, and indicate their relative importance compared with other health research efforts of the Department. The Secretary has further directed the Committee to investigate how best to integrate this planning process into ongoing HEW planning and budget activities.

In light of the Secretary's request, I would appreciate any comments you may have concerning this planning document. I hope you will share my conviction that it provides an excellent framework for discussion and further planning of health science in the United States.

Your contributions to this effort and interest in its success are most appreciated. I shall look forward to receiving your comments on the enclosed planning document. Please write by April 15 to the Executive Secretary of the HEW Steering Committee: Dr. Joseph G. Perpich, Associate Director for Program Planning and Evaluation, Building 1, Room 137, National Institutes of Health, Bethesda, Maryland 20205.

Donald S. Fredrickson, M.D.
Director

Enclosures (3)

P.S.: If you would like to receive future documents of the HEW health research planning series, please fill in and mail the enclosed postcard.

APPENDIX C

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

: PHS Agency Heads

DATE: April 9, 1980

FROM : Director, NIH

SUBJECT: Dr. Richmond's Public Health Service Agency Heads Meeting on April 11, 1980: HEW Health Research Planning

The Secretary's January 29 memorandum, which outlines her expectations for the next steps in the HEW health research planning process, will be taken up at Dr. Richmond's Public Health Service Agency Heads meeting on Friday, April 11. In that memorandum (Attachment A) the Secretary directs the HEW Steering Committee to consider all comments on the report and to suggest needed revisions; to assess the proposed initiatives, including their budgetary implications; and to make recommendations for a long-range planning process for the Department. An extra dimension of urgency and importance attaches to review of research planning at this time because of the changes in the President's budget request for Fiscal Year 1981, with rescissions for some PHS programs in the current year.

As the Secretary requested, the planning document has been published and is being circulated widely for review and comment to the Steering Committee. For your information, I am enclosing a copy of the document in the final printed version together with copies of letters transmitting it to (1) Congress, (2) the Office of Science and Technology Policy, (3) the Institute of Medicine, and (4) participants in the development of a health research strategy for HEW (Attachment B). April 15 has been set as the deadline for public comments on the document, and the Institute of Medicine should provide a report by May 1.

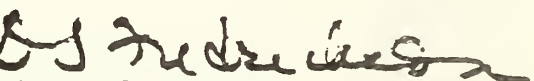
With all of this weight of unknown public comment still ahead for the Committee, and with much yet to be done in any linkages between planning and budget, it seems important that HEW Steering Committee members meet promptly to seek agreement on what further steps in the planning process should be taken. Even apart from the need to reassess the proposed research initiatives in terms of new budgetary realities, there is much to do. Committee members will want to consider how to move ahead on the current set of initiatives (including the possibility of modifying or dropping some of them), whether possible new initiatives should be added to the list for immediate or deferred implementation, and if so, with what priority in relation to the others. And finally, how to deal with various longer term planning issues that have been raised--for example, the need for new advisory mechanisms--has to be examined. (See Attachment C for a paper on health research management issues that was to have been discussed at the Secretary's Budget "Advance" meeting. It will need to be discussed by the Steering Committee.)

NIH has been looking at each of the initiatives in its planning and budgeting for fiscal years 1981 and 82, and considering the need for possible changes this year. Particular attention has been paid to the initiatives that have already been launched on a substantial scale, for example, Stabilization of the Science Base and the National Toxicology Program. Because each of the initiatives depends on interagency cooperation, it would be most helpful if Agency Heads would reassess and pin down their current perspectives on the initiatives for which they are indicated as sponsor or co-sponsor. Respective budget plans for FY 1982 are a special concern for all cooperating agencies.

Despite uncertainties in the present budget equation for all of the health agencies, possible new proposals need to be considered. For instance, from NIH appropriation hearings in the Senate, where the HEW Planning Document was examined, it seems likely that an initiative in research training (a concern of several PHS agencies) may be warranted, and that a proposal to deal with some of the resource problems of the National Library of Medicine probably would be received sympathetically. Clearly, public commentators can be counted on to come up with a number of proposed initiatives in one area or another, at least some of which will be helpful. But Committee members own ideas and priorities need to be put in place first, so that with the new budget, better decisions can be made consistent with an emphasis on strengthened research planning for HEW.

The Secretary set a June 15 deadline for a report to her. Because of recently introduced uncertainties, adjustment of that date may have to be sought. But it will be important for the Committee to make sure that the Secretary has in hand an updated set of initiatives in time to review and select from for possible emphasis in the FY 82 budget. If that much progress can be made in discussions, the Committee might also want to consider (and recommend) a new annual process for planning and budgeting of research initiatives. A further extension of the present HEW Steering Committee role is certainly one possibility. One can envision a set of annual recommendations on continuing commitments and possible new enterprises, that then could be dealt with in a special budget meeting between the Surgeon General and the Secretary. In any case, if the initiatives are to remain a part of HEW planning strategy for research, some thought to continuing process would be in order.

I see discussion of these issues at the coming Agency Heads meeting as essential in setting the agenda for any further efforts of the HEW Steering Committee.



Donald S. Fredrickson, M.D.

Attachments
A - Secretary's Memorandum of January 29, 1980, to Assistant Secretary for Health
B - Health Research Planning Document with Letters of Transmittal
C - Health Research Management Issues

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MARYLAND 20014

February 15, 1980

Dr. David Hamburg
President
Institute of Medicine
National Academy of Sciences
Washington, D. C. 20418

Dear David:

On behalf of Secretary Harris, and as Chairman of the HEW Steering Committee for the Development of a Health Research Strategy, I am transmitting for your consideration the report "Health Research Planning at HEW: Current Efforts and Proposed Initiatives." (See enclosure.) This document ends Phase II of the planning process for health research in the Department of Health, Education, and Welfare. In keeping with the Secretary's commitment to involve the research community and the public in this process to the extent possible, you and the Institute of Medicine have been important participants from the outset. I think the special IOM committee set up to review the initial HEW draft of the Health Research Principles provided an excellent critique and report. Its comments were most helpful to the Steering Committee in putting together the final set of principles approved in August.

Because of the thoughtful and effective role played by the IOM in development of the principles, I am asking that you and your committee formally review and report upon this planning document. If this is acceptable to you, I will have Joe Perpich work with Elena Nightingale in providing the Institute with the necessary support for the conduct of this study.

The planning document consists of a "Chairman's Overview Statement" (in effect, an executive summary) and two main parts: (1) a description and analysis of all HEW health research activities for FY 1980, and (2) a set of proposed "Health Research Initiatives" for 1980 and beyond. The proposed initiatives may be of particular interest, because they are experiments in cooperative research planning and management. Each relates to the recently approved health research principles. They arise through voluntary agreement among two or more HEW health agencies that share mission interest in particular health problems and see opportunities to increase the effectiveness of research on those problems through planning and coordination.

This document would not commit HEW or the Administration to a specific course of action. Clearly, however, some or all of the research initiatives can have an impact on HEW budget processes. For example, the National

Toxicology Program and the initiatives on radiation and nutrition research address significant national concerns.

Secretary Harris has directed the HEW Steering Committee to evaluate carefully all comments and to revise the planning document as necessary. She has also asked the Committee to assess the proposed initiatives and their implications for future budgets. The Committee will then set priorities among the initiatives, and indicate the relative importance of these proposals compared with other health research activities of the Department. The Secretary has further directed the Committee to investigate how best to integrate this planning process into ongoing health research planning and budget activities of HEW.

In light of the Secretary's request, I specifically ask that you and your committee consider this document in the context of your earlier critique of the draft Health Research Principles. These questions, in particular, should be addressed:

- Is the "SATT" model (Science base, Applications, Technology Transfer, and Training) a reliable and valid tool for program planning and budget development activities for all HEW health agencies? If not, what modifications are necessary to make it more useful for all of HEW? What are the limits of its applicability?

- How should the research planning process be related to budget development?

- Does the IOM have suggestions for criteria to guide the Department in choosing and allocating resources among important alternatives?

- How would the IOM recommend that the Department view the currently proposed initiatives in terms of appropriateness? priority? Would the IOM add other initiatives or make substitutions?

For a review of the kind proposed, you and your committee are uniquely constituted to reflect the wide spectrum of relevant views from the health research community.

Thank you very much.

Sincerely yours,

Donald Fredrickson

Donald S. Fredrickson, M.D.
Director

Enclosure

APPENDIX E

INSTITUTE OF MEDICINE
NATIONAL ACADEMY OF SCIENCES
2101 CONSTITUTION AVENUE WASHINGTON, D.C. 20418

DAVID A. HAMBURG, M.D.
PRESIDENT

May 15, 1980

Donald S. Fredrickson, M.D.
Director
National Institutes of Health
Public Health Service
Department of Health and Human
Services
Bethesda, Maryland 20205

Dear Don:

I am pleased to transmit to you the letter report of the Institute of Medicine Committee to Review DHEW Health Research Planning, Phase II. We were fortunate in being able to assemble a remarkably eminent committee with excellent capability to conduct this review. The Committee has provided a thoughtful analysis of the relation of the health research principles to health research planning.

In their review of the DHEW Health Research Planning Phase II document, the Committee notes both the difficulty and importance of long-range planning. They, and I, sincerely hope that their comments and recommendations will be of assistance in the continuing effort to develop a health research planning strategy for the Department.

We would be pleased to discuss the report in greater detail with you and members of your staff.

Speaking personally, I want to express my deep appreciation for the fine leadership you have provided in a difficult time. I look forward to working with you toward the advancement of health research in the future.

With very best regards,

As always,

Dave

A REVIEW OF DHEW HEALTH RESEARCH PLANNING, PHASE II

Institute of Medicine
Division of Health Sciences Policy

May 1980

Supported by National Institutes of Health
Contract No. 1-OD-0-2111

National Academy of Sciences
Washington, D.C.

NOTICE

The project that is the subject of this report was approved by the Governing Board of the National Research Council, whose members are drawn from the Councils of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine. The members of the committee responsible for the report were chosen for their special competencies and with regard for appropriate balance.

This report has been reviewed by a group other than the authors according to procedures approved by a Report Review Committee consisting of members of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine.

2101 Constitution Avenue, N.W.
Washington, D.C. 20418

Area (202) 389-6187

INSTITUTE OF MEDICINE
Committee to Review DHEW Health
Research Planning, Phase II

Chairman

Irving M. LONDON, M.D., Director, Harvard-MIT Division of Health Sciences and Technology, Cambridge, Massachusetts.

Members

Lester BRESLOW, M.D., M.P.H., Dean, School of Public Health, UCLA, Los Angeles, California.

H. Keith H. BRODIE, M.D., Professor and Chairman, Department of Psychiatry, Duke University Medical Center, Durham, North Carolina.

Theodore COOPER, M.D., Ph.D., Dean, Cornell University Medical College, New York, New York.

Joshua LEDERBERG, Ph.D., President, The Rockefeller University, New York, New York.

Neal E. MILLER, Ph. D., Professor of Psychology, Rockefeller University, New York, New York.

Arnold S. RELMAN, M.D., Editor, The New England Journal of Medicine, Boston, Massachusetts.

Henry W. RIECKEN, Ph.D., Professor of Behavioral Sciences, University of Pennsylvania School of Medicine, Philadelphia, Pennsylvania.

Mitchell W. SPELLMAN, M.D., Ph.D., Dean for Medical Services and Professor of Surgery, Harvard Medical School, Boston, Massachusetts.

Rosalyn S. YALOW, Ph.D., Senior Medical Investigator, VA Hospital, Bronx, New York.

Staff

Elena O. NIGHTINGALE, M.D., Ph.D., Acting Director, Division of Health Sciences Policy

Barbara FILNER, Ph.D., Staff Officer

Michelle TRUDEAU, B.A., Research Associate

Linda DEPUGH, Administrative Secretary

May 15, 1980

Donald S. Fredrickson, M.D.
Director
National Institutes of Health
Public Health Service
Department of Health and Human
Services
Bethesda, Maryland 20205

Dear Dr. Fredrickson:

In response to your request* to the Institute of Medicine, the Committee to Review the Department of Health, Education, and Welfare (DHEW) Health Research Planning, Phase II, submits this review of the report HEW Health Research Planning; Health Research Activities of the DHEW; Current Efforts and Proposed Initiatives (December, 1979) 1/. In accordance with our agreement with you, this is in the form of a brief letter report conveying the impressions of the Committee.

The development of broad principles to underlie health research planning was Phase I of the health research planning effort 2/. In March, 1979, at the request of DHEW, the Institute of Medicine issued a review and analysis of DHEW's preliminary formulation of the principles 3/. In your present request, you have asked the Institute to consider the Phase II planning document "in the context of [the Institute's] earlier critique of the draft Health Research Principles." You also have asked that the following questions be addressed:

- Is the "SATT" model (Science Base, Applications, Technology Transfer, and Training) a reliable and valid tool for program planning and budget development activities for all HEW health agencies? If not, what modifications are necessary to make it more useful for all of HEW? What are the limits of its applicability?

*Letter attached as Appendix 1

- How should the research planning process be related to budget development?

- Does the IOM have suggestions for criteria to guide the Department in choosing and allocating resources among important alternatives?

- How would the IOM recommend that the Department view the currently proposed initiatives in terms of appropriateness? priority? Would the IOM add other initiatives or make substitutions?

We respond to these questions briefly here.

o With regard to the SATT model, we agree that it offers, in the words of the DHEW document, "a modest beginning in developing a useful approach to the examination of all the Department's health research activities" 4/. However, we believe that the distinction between applications and transfer needs to be explained more clearly.

o With regard to relating the planning process to budget development, we believe that health research planning should be based on scientific opportunity and on long-range goals, and should precede budget development. Budget development might be viewed as subsequent short-term planning. We would suggest that budget decisions for the alternatives set forth in a planning document be made in the context of the criteria for priority mentioned in response to your third question.

o With regard to criteria to guide the allocation of resources among important alternatives, a well-conceived research plan (and budgets derived from it) would reflect the consideration, for each alternative, of research opportunity (i.e., the state of the art, the potential for new breakthroughs, and the relationships with other research problems), the associated burden of illness, the public's perception of need, and the needs of regulatory as well as research

agencies. The planners should consider the extent and the distribution of research activities, the disciplines that show special promise for advancing the public's health, problems inadequately investigated, excessive duplication of activity, and areas where personnel and/or facilities should be developed further or better utilized 5/. And at all times, a most important criterion is the scientific excellence of the research being considered 6/.

o While undoubtedly some of these factors are considered in the Phase II planning document, there is little direct evidence of such consideration in the descriptions of Initiatives 2 through 11. We find it difficult, therefore, to comment on the appropriateness of specific initiatives and on their relative priority on any basis other than opinion. Accordingly, we prefer not to comment further on these initiatives.

Some themes critical to planning were presented in the earlier Institute of Medicine critique, including the need for a "vigorous reaffirmation" of support for the health sciences, and an increased commitment to existing and new programs 7/; a "broadened concept of the health sciences" to encompass such fields as epidemiology, biostatistics, environmental science, health services research, and the behavioral and social sciences 7/; and, an "appropriate balance" between predictability of support for established investigators and opportunities for support for promising new investigators 8/. Although DHEW underscored these themes in the final Health Research Principles, we believe they are not given adequate consideration in

the Department's planning strategy to date, as presented in the Phase II planning document.

In summary, we believe that this Phase II Health Research Planning document is a useful review of current DHEW activities. We recognize that little time was available for development of a comprehensive plan. However, the Phase II document does not appear to be the product of a health research planning process such as might have been anticipated on the basis of the Health Research Principles released by the Secretary in August 1979 2/. The Phase II document may represent the beginning of a planning process. We look forward with interest to the further evolution of the process, and hope that our review will be helpful in its development.

In order to explicate more fully the concerns and issues raised above, we shall comment briefly on the Current Efforts section of the Phase II document, and comment at greater length on the SATT model, special initiative No. 1 "Stabilizing the Science Base", and the planning process in general.

Current Efforts

The first part of the DHEW report, a summary of the missions and current health research activities of relevant DHEW agencies, is a useful compendium. Its abbreviated form notwithstanding, it should be of value to the health research community in identifying potential sources of support, collaboration, or information. Its value would be enhanced by a somewhat more complete description of the principal areas of research activity in each agency. It should help to clarify the wide

array of research needs and opportunities pertinent to the broad missions of DHEW.

SATT Model

The introduction into the planning process of the SATT model (Science Base, Applications, Technology Transfer, and Training) offers, in the words of the DHEW document, "a modest beginning in developing a useful approach to the examination of all the Department's health research activities" 4/. We recognize that the model may be a useful way to classify the major thrust of funding for various programs and agencies, although some agencies may find it difficult to apply the model. The utility of the model would be enhanced by consistency in the definition of science base throughout the document. In Appendix B science base appropriately includes population-based research as well as laboratory and clinical investigations 9/. However, when stability of this same science base is discussed, only laboratory and clinical research efforts are considered 10/.

We find the SATT model somewhat confusing with regard to the distinction between applications and transfer. Applications are described as activities making research advances available to the community, while transfer activities make products, techniques, and services derived from research available for adoption 11/. We do not fully understand the difference between research advances and techniques derived from research, nor do we understand the difference between available to the community and available for adoption. These two components of the model need to be explained more clearly: as presented in Appendix B of the Phase II document, applications and

transfer do not seem to be sufficiently distinct conceptually to form separate categories.

Although DHEW considers training to be an essential component of health research, as its inclusion in the SATT model would indicate, there is only scant mention of training in the document. The committee strongly endorses inclusion of training in the model, and considers the first initiative ("Stabilizing the Science Base") an appropriate locus for detailed discussion of training. We question the wisdom of the decision (stated in that initiative) to defer a full discussion of training to "a later time" 12/. Training is important in order to provide a continuing flow of new investigators who will maintain the development of new ideas in a field. For the long term, training is integral to progress in research.

We also note here the growing importance, and need for, assessment of technology in health care. While such assessment must be supported, it should not be at the expense of funding for the science base. Further thought needs to be given to reasonable sources, such as the Health Care Financing Administration, for support of such activities.

Stabilizing the Science Base

We shall preface our remarks on this most important initiative with the fourth Health Research Principle.

> o "Present research capabilities must be sustained and enhanced to assure future health gains. Fulfillment of research goals depends on a community of researchers working with adequate resources in government and private institutions, including colleges and universities, medical and other health professional schools, and hospitals, clinics, and laboratories. This research community requires continuous and predictable support from HEW" 13/.*

*Underlining as in the final Health Research Principles.

The HEW steering committee for Phase II of health research planning selected the number of competing research project awards as the basis for establishing stability 14/. However, we have grave reservations about the specific numbers and goals chosen. There is a serious possibility that implementation of this initiative would serve to put a ceiling on growth rather than to provide a firm floor from which to build. We believe that the focus on the need for "predictable support" has been at the expense of the need that support be "sustained and enhanced".

The growth rates chosen for "modest growth", "minimal growth", and "maintenance" are too restrictive for a forward-looking document. For example, in the projections for NIH research grants (Table 10), "minimal growth" and "maintenance" represent a net decline from the Fiscal Year 1981 level for the total number of awards 15/. This is not consistent with the statement in the Health Research Principles that "present research capabilities must be sustained and enhanced". In view of the many past accomplishments and the continuing vigor of research supported by NIH, we believe that "modest growth", as presented in Table 10, is merited at a minimum.

We believe that the planning document should reflect the view that current fiscal constraints are real but may ease in the future. Although health research administrators, and the scientists engaged in research, cannot ignore current budgetary and political constraints, undue emphasis on the limitation of resources can all too easily lead to a plan of unduly

low aspiration and limited utility for the longer term. Scientific opportunity, the burden of illness, and the potential to reduce that burden of illness should be the starting point for planning. The full measure of growth that the current state of science pertinent to health can reasonably be expected to producee should be indicated. If the economy cannot sustain such growth, determination of the rate of growth that can be supported should be made with full knowledge of lost scientific opportunities and of reduced prospects for improving health. We believe that it is the explanation of these opportunities that DHEW shold provide to the President and the Congress.

Stabilization should go beyond a narrow focus on the number of research grant awards to include attention to the maintenance of institutions in which health research is carried out 6/ and to the pool of trained investigators.

According to the Phase II document, 10 percent of all principal investigators (PIs) on research project grants at NIH are new and the median age for these new PIs is 35 years 16/. The general growth in support of scientific research in the 1960s led to a significant increase in the pool of scientific investigators. These scientists would be, at present, 35-45 years old. Furthermore, because of new federal and state legislation, retirement is no longer mandatory at the age of 65. As a result of these considerations, there are a considerable number of tenured faculty members at universities and

research institutions who are not likely to retire soon. This is a barrier to the advancement, and security, of a young investigator. It would be wasteful to accept the loss of these skilled investigators who represent a major past investment and future resource. Surely a farsighted approach to stabilization should come to grips with this issue.

The Phase II planning document indicated that about half of the new PIs are not supported by NIH after about six years 16/. We are unsure how to interpret this observation. What career activities are these scientists pursuing after they no longer have research support from NIH? Is their research supported by other agencies? Are they continuing in research, but no longer as PIs? Have they continued in some science-related career activity or have they dropped out of science? Does their withdrawal from NIH sponsored research result from budgetary constraints or from the quality of their research proposals? We strongly recommend that a detailed analysis of entry into and exit from the health research community be carried out, with an assessment of the many implications of the data, before these values be accepted as predictors for future growth.

The Planning Process

The last Health Research Principle states:

- "Health research is a universal activity of great significance to all people and to future generations, and HEW research should be inte-

> grated with that conducted by other organizations in this country and abroad. The guiding standards for support of health research are scientific excellence as judged primarily by peer review, a balancing of need and technical opportunity for advancing knowledge, and conformance to sound ethical principles. To assure that HEW health research is responsive to public concerns, the public must participate in the setting of research policies and priorities" 13/.*

The criteria for eligibility as a Phase II special initiative stipulate for each initiative that "it must be a research effort; it requires participation by more than one HEW agency; it lends itself to a mechanism for research coordination; it should, if possible, project budget needs for 3-5 years; and it must relate to one or more of the approved HEW principles for health research support, and its description must identify this relationship" 17/. Regrettably, special scientific opportunity is not included in the criteria for a special initiative. Achieving cooperation and coordination among agencies, although difficult, is to be encouraged, particularly in light of economic constraints. Nonetheless, there has been too little time to develop initiatives of highest scientific merit 18/.

We believe that there are numerous other health research opportunities that could be selected according to the criteria set forth in the Health Research Principles. This planning document does not reflect the opportunities for scientific understanding and health improvement presented in the Report of the President's Biomedical Research Panel 19/ or

*Underlining as in the final Health Research Principles.

Science and Technology, A Five-Year Outlook 20/. For example, where are the excitement and promise of the great advances being made in our understanding of brain function, and the long-range promise of alleviating neurological and psychiatric disorders; our understanding of the role of blood lipoproteins and other risk factors in cardiovascular disease and the potential for their modification; our insights into the immune system and its further mobilization to prevent disease; and our understanding of the technology of recombinant DNA and its emerging value for alleviating non-genetic as well as genetic disorders?

We believe that if this Phase II planning document and its initiatives are to be useful as an experiment in the application of the principles, there must be more specific explication of the process by which these initiatives were chosen. The initiatives are concerned with research issues that are potentially of value to the nation, but it is difficult to judge whether they should be research programs of high priority. Although it was suggested in the Phase II document that each agency identify short- and long-term goals 17/, this information is not provided. What are the priorities of the individual agencies? What criteria are used by the agencies in selecting their proposals and how do these criteria relate to the Health Research Principles? On what basis was a final selection made among the interagency initiatives eligible for inclusion in the planning document?

Although these initiatives are intended as limited experiments in the application of the principles to interagency efforts 21/, it is the committee's concern that they may be misinterpreted as the final research

agenda of DHEW. The requirement of participation by more than one agency may not provide assurance of scientific importance or quality. What is needed is an effective research planning mechanism for HEW that uses points of contact among agencies to help provide a comprehensive view of the research enterprise. The planning mechanism should allow enough time for adequate deliberation and should provide sufficient flexibility to accommodate revision on the basis of experience.

The time needed to develop a well-reasoned, comprehensive and constructive health research plan had been of concern 25/. We believe the time was indeed inadequate and the present document is inevitably incomplete and unsatisfying. You asked us to review this Phase II document in the context of the previous Institute of Medicine critique. We note that in addition to the concerns expressed throughout this review, several important issues raised in the earlier analysis still are inadequately resolved or are not considered. These include

- "the promotion of productive interaction between public and private health research activities;"
- "the relationship of health research programs and needs in agencies such as the Veterans Administration, the National Science Foundation, and the Department of Defense and Energy to health research programs and priorities in DHEW;"
- "organizational aspects of NIH, including both its intramural and extramural programs, and the strengths and limitations of the categorical institute structure;"
- "the locus of responsibility within DHEW for fundamental research in areas other than the biomedical sciences;" and
- "mechanisms by which the research needs of the regulatory agencies in particular are to be met" 8/.

It is still apt to point out that:

> "As regards the process being used to develop the plan, we are impressed by the desire of DHEW, and NIH in particular, to incorporate public review and discussion as this process proceeds. We believe, however, that optimal mechanisms have yet to be established to provide for constructive interaction in this process among the public, policymakers, and the health sciences community" 8/.

Summary

In summary, we consider this document not to be a research plan, but an exploratory step toward the difficult task of planning.

1. A review of current efforts has been accomplished and is useful, albeit incomplete.

2. The SATT model is a "modest beginning". Its utility would be enhanced by a clear recognition of the inclusion of population based research in the science base component, and by a clarification of the distinction between applications and technology transfer. Assessment of technology in health care is a growing and important need that will require new sources of funds.

3. "Stabilization of the Science Base", as presented in the first special initiative, is too restrictive for a forward-looking document. Long-range health research planning should be based mainly on scientific opportunity and burden of illness, so that in the face of fiscal constraints, informed choices can be made. The planning document should reflect the full measure of growth that the current state of science can reasonably be expected to

produce. The President and Congress may decide that the economy cannot sustain such growth, but such decisions should be made with full knowledge of the lost scientific opportunities and of the consequences to health in the future.

- o "Modest growth" (based on previous levels of support and rates of growth) should serve as the floor for planning. "Minimal growth" and "maintenance", as projected in the initiative, are not stabilization since they entail a decline in the total number of grant awards.
- o Additional analysis of entry into and exit from the pool of health research manpower should be carried out before the data presented in the current planning document are deemed acceptable as predictors of future patterns. Attention should be given to institutions and to training for research, essential components of effective long-term stabilization.

4. The planning process itself still needs to be developed. The following points should be considered in the selection of health research initiatives.

- o Scientific opportunity and the burden of illness along with the public's perception of need and the needs of regulatory agencies should be among the main criteria for priority.

- o The application of the health research principles and the details of the application of the criteria for priority should be presented explicitly in the planning document.
- o The health research principles should be in evidence at the level of agency selection of priority as well as in the final selection of Departmental priorities.
- o The process of determination of scientific opportunity should include participation of the health research community.
- o Scientific excellence must be a principal criterion for the support of research.

At this point we offer another suggestion for future planning documents. In order to avoid confusion and misunderstanding, terms should be defined at the beginning of the document. The terms "planning" and "stabilization", for example, are subject to a variety of interpretations. (Health research planning can be viewed as research planning from a substantive perspective or as short-term budget allocation.)

A major effort is needed to develop a health research plan that will form the basis for a national policy. DHEW should develop such a plan with whatever assistance is required from the scientific community and the public.

We recognize how difficult this task of planning may be, especially in view of the need to coordinate the efforts of different agencies, many with significantly different missions. We are justifiably proud of the health research achievements of DHEW, and especially of NIH, in past decades. It is in light of these achievements and of the potential for even greater contributions to the health of our society in the future that the current document falls short of our expectations and hopes.

Sincerely,

Institute of Medicine Committee
to Review DHEW Health Research
Planning, Phase II

Irving M. London, M.D., Chairman

Lester Breslow, M.D, M.P.H.
H. Keith H. Brodie, M.D.
Theodore Cooper, M.D., Ph.D.
Joshua Lederberg, Ph.D.
Neal E. Miller, Ph.D.
Arnold S. Relman, M.D.
Henry W. Riecken, Ph.D.
Mitchell W. Spellman, M.D, Ph.D.
Rosalyn S. Yalow, Ph.D.

References

1. HEW Health Research Planning, Phase II; Health Research Activities of the Department of Health, Education, and Welfare; Current Efforts and Proposed Initiatives, A Report of the HEW Steering Committee for the Development of a Health Research Strategy, December 1979. NIH Publication No. 80-2053.

2. HEW Health Research Principles, Volume 2; Documents Relating to the Development of Final Health Research Principles for the Department of Health, Education, and Welfare; December 1978-August 1979. October 1979. NIH Publication No. 80-2057.

3. Institute of Medicine. DHEW's Research Planning Principles: A Review. Washington, D.C.: National Academy of Sciences, March 1979.

4. Reference 1, page 15.

5. Reference 3, pages 57-58.

6. Reference 3, page 7.

7. Reference 3, page 5.

8. Reference 3, page 8.

9. Reference 1, page 176.

10. Reference 1, page 87.

11. Reference 1, page 177.

12. Reference 1, page 88.

13. Reference 2, page 9.

14. Reference 1, page 89.

15. Reference 1, page 91.

16. Reference 1, page 31.

17. Reference 1, page 84.

18. Reference 1, page 229.

19. Report of the President's Biomedical Research Panel, Appendix A, The Place of Biomedical Science in Medicine and the State of the Science. April 1976. DHEW Publication No. (OS) 76-501.

20. National Academy of Sciences. Science and Technology, A Five-Year Outlook. San Francisco: W.H. Freeman and Company, 1979.

21. Reference 1, page 83.

22. Reference 3, page 9.

APPENDIX F

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

TO : PHS Agency Heads

DATE: MAY 22 1980

FROM : Director
National Institutes of Health

SUBJECT: June Meeting of the HHS Steering Committee

The next meeting of the HHS Steering Committee will be held on June 25 from 10:00-11:30 a.m., in the Hubert H. Humphrey Building, Room 337A. The purpose of this meeting will be two-fold:

- To review agency commitments to interagency research initiatives for FY 1981 and as proposed for FY 1982, taking into account the revised Presidential budget for FY 1981. At the meeting the Committee will analyze and discuss research priorities and specifically seek agreement on initiatives--whether to add new ones, or drop current ones--in the light of changing budget and program perspectives.

- Review and modify as necessary a proposed outline for the next HHS planning document, to carry forward the development of a strategy for support of health research within the Department.

The Steering Committee staff have been meeting to develop a draft guidance for a proposed new planning document and to consider how best to provide the information requested in the Secretary's memorandum of January 29.

The planning document tentatively would include the following:

- A description of health research planning processes currently used by each agency represented on the Steering Committee.

- A summary of agency plans for research including commitments to the various interagency research initiatives.

- Proposals for future directions in Departmental health research planning, based in part at least on analysis of public response to the Phase II planning document and the IOM critique.

At the Secretary's request, I will meet with her on May 29 to brief her on a number of issues. The agenda calls for a discussion of health research planning. Therefore, I would appreciate any comments you may

have on matters raised in this memorandum prior to May 29. Because of the needed re-thinking of priorities touched off by revisions to the President's FY 1981 budget, I will ask the Secretary to extend the deadline for the Committee's response to her questions regarding the Phase II planning document from June 15 to September 15.

Thank you very much.

Donald S. Fredrickson, M.D.

cc: Assistant Secretary for Management and Budget
Assistant Secretary for Planning and Evaluation
Administrator, Health Care Financing Administration

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

APPENDIX G

TO : HHS Steering Committee

DATE: June 2, 1980

FROM : Assistant Secretary for Health and Surgeon General
Chairman, HHS Steering Committee

SUBJECT: June 27 Meeting of the HHS Steering Committee

On Thursday, May 29, we met with Secretary Harris to brief her on a number of actions involving the National Institutes of Health, the Public Health Service, and the Department. One item discussed was the proposed agenda for the next meeting of the HHS Steering Committee that was reviewed at a meeting of PHS agency heads on May 23. The Steering Committee meeting is scheduled for Friday, June 27, from 2:00 to 4:00 p.m., in the Humphrey Building, Room 403A.

As you know, the Secretary originally set a June 15 deadline for preparation of the Phase III planning document (Attachment A). In briefing the Secretary, we noted that the HHS Steering Committee at its meeting in June would (1) review agency budget commitments to interagency health research initiatives and (2) approve plans for a Phase III planning document. Because the revisions of the President's FY 1981 budget have caused some changes in agency plans, we asked that the June 15 deadline be extended. The Secretary has asked that the planning document be prepared by July 15 to meet her Budget Policy Committee timetable. (July 21-24 is the date set for the BPC to define the budget mark it will propose to the Secretary for each principal operating component.) She noted that last year's planning document was very useful in budget presentations to OMB, and she expects to use this document similarly.

In order to meet the Secretary's request, we will need planning and budget information from each agency by c.o.b. Monday, June 9, so that a draft of the planning document can be made ready for the Steering Committee's review on June 27. (See Attachment B for guidance.)

The major order of business at our meeting will be to review interagency commitments to (1) current interagency research initiatives and (2) proposed initiatives. (See Attachment C for our memo to the initiative coordinators requesting an update on each initiative contained in the December 1979 Phase II document.) Thus, we will need for background purposes a breakout of the research portion of each agency's FY 1981 revised President's budget. Also, in order to make judgments about the initiatives, we will need a breakout of each agency's budgeted commitment to the health research initiatives proposed in the December 1979 Phase II document. In addition, for purposes of the Secretary's budget review, we will need each agency's commitments to the proposed initiatives for FY 1982. Finally, new agency initiative proposals must also be considered. (For example, the Secretary

indicated in our meeting that research manpower should be included, as the Congressional Appropriations Committees had indicated their interest in this as a possible initiative.) At our meeting we will have to reach agreement on the initiatives--whether to add new ones or drop current ones--in the light of your changing budget and program perspectives.

NIH will again serve as the PHS agency focus for receiving the material and preparing the document. Dr. Joseph G. Perpich, Executive Secretary of the Committee, and his staff will collate the information received from your agency and prepare the first draft of the proposed new planning document. The NIH budget office will contact your budget offices to develop information. Close coordination between planning and budget staffs of each of the agencies will be required.

Obviously, we need your full cooperation to meet the Secretary's deadlines. The Secretary intends to use the new planning document to review interagency health research initiatives for FY 1982 as part of her budget development. Working together, we can develop a good picture of health research activities in the Department in terms of the President's revised budget for FY 1981 and of individual agency commitments to interagency initiatives. We must also reach some tentative agreement on how to plan for future health research activities in the Department. (See Attachment D for the Institute of Medicine's critique of the Phase II planning document.) Thus, it is essential that you, or a designee who can speak for you, come to the June 27 meeting and present your agency's perspective on these issues. Thank you very much.

Julius B. Richmond, M.D.

Donald S. Fredrickson, M.D.

4 Attachments

W/O Tab (Attachment) D

APPENDIX H

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MARYLAND 20205

June 24, 1980

MEMORANDUM TO: Members, HHS Steering Committee for the Development of a Health Research Strategy

FROM: Chairman

The HHS Steering Committee will meet on Friday, June 27, in the Humphrey Building, Room 403-A, from 2 to 4 p.m., to review a draft (enclosed) for the HHS Health Research Planning Document--Phase II (Final).

In our June 2 memorandum to you, Dr. Richmond and I relayed the Secretary's request that the planning document be prepared by July 15 to meet her Budget Policy Committee timetable. On the basis of the outline developed by Steering Committee Staff, and in response to the Secretary's request, the planning document consists of the following:

- Part One: For each agency, a summary description of the current research planning processes plus a summary of the agency's amended research budget for FY 1981 as proposed by the President.

- Part Two: A revised Health Research Initiatives section, including the original 11 initiatives updated to show current status and proposed commitment levels for FY 1982, plus four new proposed initiatives.

Part One consists of relevant information supplied by each agency; further editorial work may be required on some sections. The initiatives in Part Two are expected to be the focus for Committee review and discussion. Main concerns will be to review each agency's commitments to current interagency research initiatives, and to assess agency interest, if any, in proposed new initiatives, including willingness to commit resources to these initiatives in FY 1981 and 1982. Budget and planning officers from each agency have worked together to develop the required commitment data.

To sum up, the job of the Steering Committee will be to ascertain each agency's proposed commitment to the various initiatives, and to find out how the agency ranks them relative to its other research program priorities. If the Committee can agree reasonably on the merit and promise of the several initiatives, and respective agency interests in them, the Secretary would find this information extremely useful in developing the Department's FY 1982 budget requests for the initiatives.

On the basis of decisions reached by the Steering Committee, Dr. Richmond and I will revise the document and send it to the Secretary on Tuesday, July 15, for her review. Depending on decisions reached in the Secretary's budget review, the document may need to be revised again prior to submission of the Department's budget request to OMB. The document ultimately should be released at the time of the President's budget message to Congress in January.

I believe that we have achieved for the present a limited but still useful health research planning process for the Department, based on interagency health research initiatives, and with a clear tie-in to budget channels. This process could be taken up again next year in the same fashion we have now set. With this much more or less established, the Steering Committee needs to consider how best to assure continuity and effectiveness of this process for the future. One useful step in that direction would be to assign leadership to the Surgeon General, who would chair the Committee.

Dr. Richmond and I look forward to discussing the document, the initiatives, and the proposed processes for the future at our meeting on Friday. Thanks very much.

Donald S. Fredrickson, M.D.
Director

Enclosure

HHS STEERING COMMITTEE FOR THE DEVELOPMENT OF A HEALTH RESEARCH STRATEGY

Minutes of Meeting
June 27, 1980

The HHS Steering Committee for the Development of a Health Research Strategy held its ninth meeting on Friday, June 27, from 2:00 to 4:00 p.m., in Room 403A of the Hubert H. Humphrey Building. (See Attachment 1 for list of attendees.) Dr. Fredrickson, Director, NIH, chaired the meeting.

Introduction and Overview

Dr. Fredrickson began by calling attention to the January 29 memorandum which outlined the Secretary's expectations for the next steps in the HHS research planning process. (See Attachment 2.) In that memorandum, the Secretary directed the HHS Steering Committee to consider all comments on the report and to work out necessary revisions; to assess the proposed initiatives, including their budgetary implications; and to make recommendations for a long-range planning process for the Department. The planning document was subsequently distributed for comment to participants in the development of a health research strategy, as well as to the Institute of Medicine, the Office of Science and Technology Policy, and the Congress. Approximately 20 letters were received. The IOM's critique was referred to the Committee on May 15.

Throughout the spring, the HHS Steering Committee staff has been working on the revisions to the document. The current version consists of two parts:

- A summary description of each agency's current research planning process, plus a summary of the agency's amended research budget for FY 1981.
- A revised health research initiatives section, including the original eleven initiatives which have been updated to show current status and proposed commitment levels for FY 1982, together with four new proposed initiatives.

HHS agencies have in fact benefited from the planning exercise to date, according to Dr. Fredrickson. The process has facilitated the coupling of planning and budgeting within and among agencies, an important need at all levels of program direction. The process has now led to limited but real interagency planning/budgeting for health research--something rarely accomplished before at HHS. In Dr. Fredrickson's estimation, the research initiatives, which represent cooperative attacks on priority problems of the Department, are a feasible and useful point of departure

for HHS health research planning. They are limited in scope, couple easily to budget presentations, and their number can be added to or decreased in the light of resource decisions by the Secretary, OMB, or the Congress.

The planning document released earlier this year for public review was based on the research principles announced by the Secretary in August 1979. It had good elements but was uneven as a whole, and reflected Committee inexperience in interagency planning. It emphasized the SATT model for identifying the purposes of resource allocations (Science Base, Applications, Technology Transfer and Training), which, based on comments received, is no longer emphasized as the unitary model for the Department. In the Committee's planning process, it was not possible to designate specific priorities for each initiative relative to the others, for individual agency missions, budgets, and plans were all affected. Issues so close to the bone can't reasonably be settled by a majority vote among members of a committee of equals. Ultimately, priorities will be determined by the Secretary, the President, and the Congress. Note, though, that the budget displays in the document reflect the amount that each agency feels it can dedicate to specific initiatives in fiscal years 1981 and '82, given certain assumptions about agency funding levels. Such commitments are in effect an expression of priority. Thus, the present revisions correspond with the Secretary's wishes as expressed in her memorandum of January 29. To sum up, the process had several ostensible merits: (1) it brought together budget and planning, (2) the proposed initiatives signaled to the Congress the President's commitment to fundamental science, (3) trans-Institute coordination has been succeeded by trans-agency cooperation, and (4) budget planning within the Department has been opened to public scrutiny.

Committee Discussion

Part I of the planning document, "Health Research Planning at HHS," was approved by the Committee without revision. For Part II, "Special HHS Health Research Initiatives," Dr. Fredrickson asked each of the agencies to review the initiatives to determine whether the agencies do indeed support the budget levels indicated in the proposals.

Mr. Bladen then inquired into the nature of the budget planning exercise as regards the initiatives. Is it anticipated that the Secretary may approve these proposals, yet not increase individual agencies' budgets, so that these agencies will need to reprogram money? Or was the budget planning to be done at the margin, with the Secretary providing add-on monies to a particular initiative without disturbing the individual agency's budget as proposed for her review? In Dr. Fredrickson's view, selective budget increases for the initiatives over and beyond current agency commitments would of course be at the Secretary's discretion, and would be welcome. But certainly it wasn't his expectation that the initiatives would take automatic precedence over other items in individual agencies' budgets. The initiatives process is not well enough established yet to be used for a fundamental reordering of agency priorities.

Mrs. Hanft agreed that indeed the process had not yet been formalized, and that many agencies had made commitments in other areas including interagency initiatives not related to the present effort. Mrs. Hanft did not believe that the Secretary should act on these initiatives alone, except where there may be possibilities for slight budget increments for the initiatives. She also noted that the initiatives should take into account the magnitude of problems being addressed, and questions of scientific opportunity, state-of-the-art, and the like. She believed this was important to the Secretary's understanding of the initiatives in terms of the breadth and depth of the problems being attacked. There was general agreement that some of the initiatives needed stronger or clearer descriptions on these points. Mr. Carson said that for all of the initiatives, another look would be taken at the sections describing magnitude of the problem and the nature of the scientific opportunities seen. These sections would be strengthened where possible now. Moreover, in the next planning document cycle, these sections would be emphasized further.

Dr. Lave concurred with Mrs. Hanft and noted that for the present these initiatives largely reflect a biomedical and behavioral orientation. The social and economic sciences of special interest to HCFA and NCHSR are not well represented in the initiatives.

Mrs. Hanft suggested that when the document is forwarded to the Secretary it should be emphasized that these initiatives largely reflect the heavy investment of the NIH and ADAMHA in health research, and that the Secretary should be aware of other major health initiatives that are before her, such as the long-term care initiatives which involve several agencies and include heavy emphasis on health services research. Dr. Lave seconded Mrs. Hanft's suggestion and recommended that a statement to this effect be included in the transmittal memorandum and the document's introduction. Dr. Fredrickson and the Committee agreed that this would be done. Dr. Fredrickson pointed out, however, that if the Committee's planning process worked effectively, there should be more research stimulated in HHS agencies generally, and specifically in those agencies such as HCFA that don't have a primary mission in research.

Finally, Ms. Jones said that the present document must be clearly distinguished from the one released in January, as it differs greatly from the earlier version. It was agreed that appropriate differentiations would be made.

Dr. Fredrickson then suggested the Committee review the four new research initiatives which were being proposed. These were: (1) Accelerated Development of New Vaccines, (2) Research on Prevention and Control of Hypertension, (3) Prevention of Birth Defects, and (4) Research Training.

Accelerated Development of Vaccines

Dr. Jordan summarized the proposed initiative (see report for initiative text). Mrs. Hanft raised a general question regarding this and other initiatives in terms of (1) what is new that would be done, and (2) what is

old or currently being done that would be done even were there to be no initiative in this area. There was a need to clarify this in the initiatives if they were indeed to be called initiatives. What is truly new and what is merely ongoing ought to be clearly differentiated. Dr. Fredrickson responded by noting that these initiatives need not commit new or additional investments but they present a special organized framework for the annual HHS health research plan and identify interagency initiatives for emphasis by the Secretary, the President, and the Congress. Mr. Carson noted that the National Toxicology Program initiative was launched out of phase with regular budget development cycles and without specific resource add-ons. It began with the identification of pertinent testing activities in several agencies (plus related resources) which were then grouped loosely under an NTP framework for better coordination. As the NTP has evolved, it has assumed a new program emphasis, with increased budgets. Thus, while initiatives may become a catalyst for program enhancement and larger budgets, the key element is not budget, but interagency coordination and cooperation.

Dr. Goldstone said this ought to be clarified in the introduction to assure that the reader is not misled into believing that these are necessarily new programs. Dr. Richmond pointed out that the model of the NTP was a good one. This program, organized to be responsive to the Congress and the White House, has turned into a productive institutional mode. Thus, the initiative could be considered as subtly beginning an emphasis that may grow and be nurtured into a program far different from what had originally been conceived. The Committee approved the new vaccine development initiative as a sound one noting its promise in addressing problems of great magnitude and its timeliness in terms of scientific opportunity.

Research on Prevention and Control of Hypertension

Dr. Moskowitz reviewed this initiative proposal (text of proposal in report). Dr. Lave, Mrs. Hanft, and others observed that this was an excellent initiative but that it came too late for agencies to have an opportunity to consider budget commitments. Ms. Jones asked how it related to the health prevention and promotion budget initiatives, which would include hypertension as one aspect of those initiatives. There was general Committee agreement that this initiative had merit but could not yet be characterized fully as a budget planning initiative. It was agreed that a special category (planning status?) would be created for the initiative so that it would be included in the revised planning document.

Prevention of Birth Defects

Dr. Kretchmer summarized this initiative (text of proposal in report). Mrs. Hanft pointed out that this proposal should take into account related efforts such as the conferences on maternal care and caesarean sections. Drs. Bridbord and Dowdle pointed out that this initative relates in a major way to the NIOSH initiative on "Prevention of Reproductive Effects Due to Workplace Hazards." Dr. Fredrickson agreed that there is a need to clarify how this initiative differs from or relates to the other initiatives.

Dr. Fredrickson suggested that perhaps this initative should be deferred for the present. However, Dr. Richmond said that its importance will become more and more apparent in the next decade as infant mortality rates fall and pressures rise for dealing with congenital malformations. He felt that this initiative should, if possible, be retained. Dr. Fredrickson acknowledged the point of this and suggested that Drs. Kretchmer, Foege, Dowdle, and Bridbord might need to meet to try to deal with the organizational problems and work together to see if this proposal can be included in one form or another.

Research Training

Dr. Merritt summarized this initiative (see text of proposal in report). Mrs. Hanft said that her office would like to join this initative or at least that some reference be made to health services research training. The FY 1981 appropriation specifically provides authority for the beginning of a training program in this area. The Committee agreed and Mrs. Hanft promised to provide appropriate text. The initiative was then approved by the Committee.

After discussion of the new initiatives, the Committee turned to a consideration of the earlier initiatives. Several Committee members stated that they would like to join the established stabilization initiative--specifically CDC/NIOSH and FDA. Dr. Kramer noted that the text should include NIAAA and NIDA as participating in this particular initiative. Dr. Fredrickson stated that any HHS agency with investigator-initiated health research project grants is welcome to join the initiative. The Committee then approved without revision the rest of the eleven initiatives.

Conclusion

The Committee approved the planning document subject to agreed-upon revisions. Committee members concurred in the view that the process now set in place responds to several of the points raised by the public and the IOM, and, moreover, fulfills the mandate of the Secretary's January memorandum. The Secretary may now want to consider whether the health research planning process ought to be continued and whether it would be useful to produce an annual planning document for release at the time of the President's budget submission to the Congress. Such a document might be similar to the present one and consist of (1) a summary of research plans of the agencies, and (2) special interagency research initiatives for the next fiscal year as proposed in the President's budget.

Respectfully submitted,

Joseph G. Perpich, M.D., J.D.
Associate Director for
Program Planning and Evaluation

National Institutes of Health
Bethesda, Md. 20205
July 17, 1980

LIST OF ATTENDEES
Meeting of June 27, 1980

ATTACHMENT 1

MEMBERS

Office of the Assistant Secretary for Health

Dr. Julius B. Richmond
Assistant Secretary for Health
and Surgeon General

Office of Health Research, Statistics, and Technology

Mrs. Ruth Hanft
Deputy Assistant Secretary for
Health Research, Statistics,
and Technology

Food and Drug Administration

Dr. Jere E. Goyan
Commissioner

STAFF

Office of the Secretary

Mr. Christopher Bladen
Director of Hea'th Evaluation
Office of Planning and Evaluation

Ms. Cheryl Austein
Office of the Assistant Secretary
for Planning and Evaluation/Health

Health Care Financing Administration

Dr. Judith Lave
Director, Office of Research

Office of the Assistant Secretary for Health

Ms. Georgi Jones
Director, Division of Health,
Research and Prevention
Office of Health Planning and
Evaluation

STAFF (Cont.)

Alcohol, Drug Abuse and Mental Health Administration

Dr. Charles Krauthammer
Director, Division of Science

Center for Disease Control

Dr. Walter Dowdle
Assistant Director for Science

Dr. Kenneth Bridbord
Director, Office of Extramural
Coordination and Special Projects
National Institute for Occupational
Safety and Health

Health Resources Administration

Dr. Lyman Van Nostrand
Director, Division of Planning
Office of Planning, Evaluation
and Legislation

Health Services Administration

Mr. Ronald Carlson
Associate Administrator for
Planning, Evaluation and Legislation

OTHER

Dr. Peter Kramer
Medical Officer, Division of Science
Alcohol, Drug Abuse, and Mental
Health Administration

Ms. Lana Chay
Executive Secretariat, OS

NATIONAL INSTITUTES OF HEALTH

Office of the Director

Dr. Joseph G. Perpich
Associate Director for
Program Planning and Evaluation

Mr. Bruce F. Carson
Deputy Associate Director for
Program Planning and Evaluation

Dr. Solomon Schneyer
Director
Division of Program Analysis, OPPE

Dr. Doris Merritt
Special Assistant to the Director

National Heart, Lung, and Blood Institute

Dr. Jay Moskowitz
Director, Office of Program
Planning and Evaluation

Mr. Michael White
Director, Office of Prevention,
Education and Control

National Institute of Allergy and Infectious Diseases

Dr. William Jordan
Director, Microbiology and
Infectious Diseases Program

National Institute of Child Health and Human Development

Dr. Norman Kretchmer
Director

Note: Members of the HEW (HHS) Steering Committee Staff met frequently to assist the work of the Steering Committee. The full Staff met on April 15 and 19 and on June 20 under the aegis of Dr. Joseph G. Perpich, Associate Director for Program Planning and Evaluation, and Executive Secretary for the Committee.

•U.S. GOVERNMENT PRINTING OFFICE: 1981-0-720-020/4635

NIH Publication No. 81-2319
December 1980